Cochlear™

# Nucleus® cochlear implants

Physician's Package Insert

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This document contains important information such as indications and contraindications that applies to the following cochlear implant systems:

- Nucleus Freedom® implant with Contour Advance® electrode — CI24RE (CA)
- Nucleus Freedom® implant with straight electrode — CI24RE (ST)

# Contents

# 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 system.

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

# Indications

The cochlear implant is intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve.

## Adults

Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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 tape-recorded tests of open set sentence recognition.

## Children

The cochlear implant system is intended for use in children 9 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids. Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test. In older children, limited benefit is defined as ≤ 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.

# Contraindications

A cochlear implant is not indicated for individuals who have the following conditions:

1. Deafness due to lesions of the acoustic nerve or central auditory pathway
2. Active middle ear infections
3. Absence of cochlear development
4. Tympanic membrane perforation in the presence of active middle ear disease.

# Warnings

## Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the cochlear implant. Warnings for specific treatments are given below.

### Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of a cochlear implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~0.5 in.) from the extracochlear electrodes.

### Diathermy

Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

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

### Neurostimulation

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

### Electroconvulsive therapy

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

### Ionising radiation therapy

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

## MRI safety information


The Cochlear Nucleus CI24RE (CA) and CI24RE (ST) implants are 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide


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

## Pediatrics

To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist should be present during surgery for infants implanted under 12 months of age.

## Meningitis

Prior to implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk. In addition, certain preoperative conditions may increase the risk of meningitis with or without a cochlear implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

## Loss of residual hearing

Insertion of the electrode into the cochlea will result in complete loss of residual hearing in the implanted ear.

## Long term effects of electrical stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

## Small parts hazard

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

## Battery ingestion

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If swallowed, seek prompt medical attention at the nearest emergency center.

## Head trauma

A blow to the head in the area of the cochlear implant may damage the implant and result in its failure. Young children who are developing their motor skills are at greater risk to receive an impact to the head from a hard object (e.g. a table or chair).

## Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort. Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears). Use of the rechargeable battery is contraindicated in patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

## Overheating

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

The manufacturer only recommends the use of zinc air batteries as they have been determined to be safe in recommended use conditions and provide an appropriate power source for the CP810 sound processor.

The CP810 is not intended to be used with silver oxide batteries. In some circumstances, the use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device. In addition, use of silver oxide batteries may damage your processor.

# Precautions

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

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

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

Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user. If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left, and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

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

Do not store the processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).

The processor's sound quality may be intermittently distorted when you are within approximately 1.6 km or 1 mile of a radio or television transmission tower. Additional sources of interference include, but are not limited to:

- Security systems
- Industrial machinery and power systems
- Mobile communications equipment (including cellular telephones)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

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

## Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off the processor when in the vicinity of one of these devices.

The materials used in the cochlear implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

## Electrostatic discharge

A discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the processor.

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

Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

## Mobile telephones

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

# Adverse events

The following information summarises adverse events for adults and children implanted with the Nucleus 24 cochlear implant.

## Adults

Adult safety data are based on a total of 133 patients implanted with the Nucleus 24 during the adult clinical investigation at 27 U.S. sites. 20 patients experienced either a medical/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

# Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

## Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

## Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

## Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

# Results of clinical studies

The clinical study results contained in the Physician's Package Insert reflect clinical trials conducted with the Nucleus 24 straight array.

## Adults

### SPrint™ (body worn) processor

Effectiveness of the Nucleus 24 system using the SPrint body worn processor was assessed by comparing the speech perception abilities of 67 postlinguistically deafened adults preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after three months of device use. Postoperatively, the body worn SPrint processor was programmed to implement the Spectral-peak (SPEAK) speech processing strategy. Recorded measures of open set sentence recognition were presented in quiet using City University of New York (CUNY) and Hearing in Noise Test (HINT) Sentences. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). Open set speech recognition was also assessed over long-distance telephone lines using Central Institute for the Deaf (CID) Everyday Sentences of Speech Test and the Psycho-Acoustic Laboratory Sentences (PAL). Recorded measures of open set, monosyllabic word recognition (Consonant-Nucleus-Consonant (CNC) Words) were presented in quiet. Due to the high levels of performance exhibited by adults using the Nucleus 24, more simple measures of lipreading enhancement and closed set speech perception were not included in the evaluation battery. Individual subject results were analysed using a binomial statistical model.

### Hearing-only, open set sentences in quiet

- After three months of experience with the Nucleus 24, almost all recipients (66/67; 98.5%) demonstrated significant improvement in open set sentence recognition (CUNY) compared to their preoperative performance with hearing aids. All individuals demonstrated significantly above-chance sentence recognition. Recipients recognised an average of 78% of words in sentences, with a median score of 87%. Approximately half of the recipients (49.3%) recognised 90% or more words and approximately two-thirds (62.7%) recognised 80% or more words.
- Recipients rapidly developed high levels of open set speech perception after limited experience with the Nucleus 24. Average sentence recognition (CUNY) increased from 56% to 65% to 78% and median scores increased from 58% to 72% to 87% after two weeks, one month and three months of device use, respectively. After only two weeks, approximately one-third (31.3%) of the recipients recognised 80% or more words. After only one month, approximately half (47.8%) of the recipients recognised 75% or more words.
- After three months of experience with the Nucleus 24, almost all recipients (63/67; 94.0%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) compared to their preoperative performance with hearing aids. Almost all individuals demonstrated significantly above-chance speech recognition. Recipients recognised an average of 60% of the words in these more difficult sentences, with a median score of 63%. Approximately one-third of the recipients (35.8%) recognised 75% or more words.

### Hearing-only, open set sentences in noise (+10 dB Signal-to-Noise Ratio (SNR))

After three months of experience with the Nucleus 24:

- Almost all recipients (61/66; 92.4%) demonstrated significant improvement in the recognition of recorded, open set sentences (CUNY) in the presence of background noise, compared to their preoperative performance with hearing aids. All but one recipient demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' listening situations (background noise), recipients recognised an average of 59% of the words, with a median score of 67%. One-third of the recipients (36.3%) recognised 75% or more words and approximately one-half of the recipients (47.0%) recognised 70% or more words.

### Hearing-only, open set words in quiet

After three months of experience with the Nucleus 24:

- 88% of recipients (59/67) demonstrated significant improvement in the recognition of recorded, open set monosyllabic words compared to their preoperative performance with hearing aids. Monosyllabic word recognition ranged from 0% to 80%.
- Recipients recognised an average of 37% of the words, with a median score of 36%. 18% of the recipients (12/67) recognised 60% or more words and 28% of recipients (19/67) recognised 50% or more words.

## Telephone testing

All telephone testing was administered over long-distance telephone lines using recorded, open set sentence measures (CID and PAL sentences). Under these difficult listening conditions, after three months of experience with the Nucleus 24:

- 91% of the recipients (61/67) demonstrated significant improvement in the recognition of open set sentences (CID) compared to their preoperative performance with hearing aids. Almost all recipients (65/67; 97%) recognised these sentences at significantly above-chance levels. 79% (53/67) demonstrated significant improvement in the comprehension of open set sentences (PAL) compared to their preoperative performance with hearing aids.
- Recipients scored an average of 60% and 58% on CID and PAL Sentences, with median scores of 66% and 65%, respectively. Approximately half of the recipients (47.8%) recognised 70% or more of recorded words in sentences (CID), and 21% of recipients recognised 90% or more words. Approximately a quarter (23.9%) of the recipients correctly answered 90% or more of recorded questions (PAL), and approximately half (50.8%) correctly answered 70% or more questions.

## ESPrit™ (ear level) processor

After a minimum of three months experience with the SPrint processor, 36 subjects were fitted with the ESPrit ear level processor (programmed to implement the SPEAK speech processing strategy) and speech perception was evaluated following one month of ESPrit use. Recorded measures of open set sentence recognition were presented in quiet and in the presence of background noise (+10 dB SNR), at a level that was moderately difficult for the typical cochlear implant recipient. Recorded measures of open set word recognition were presented in quiet. ESPrit performance was compared with each subject's preoperative baseline, as well as with the SPrint postoperative baseline. The evaluation measures for the ESPrit were the same as those used to assess the SPrint, except that telephone use with the ESPrit was not assessed. Individual subject results were analysed using a binomial statistical model.

### Hearing-only, open set sentences in quiet

- Almost all recipients (34/36; 94.4%) demonstrated significant improvement in the recognition of open set sentences (CUNY) using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 79.6% of the words in sentences, with a median score of 91%.
- All recipients tested (35/35; 100%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 63.4% of the words, with median score of 65%.

### Hearing-only, open set sentences in noise (+10 dB SNR)

- Almost all recipients (32/36; 88.9%) demonstrated significant improvement in the recognition of open set sentences (CUNY) in the presence of background noise using the ESPrit compared to their preoperative performance with hearing aids. All but four recipients demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' situations (background noise), recipients recognised an average of 57.9% of words in sentences, with a median score of 64%.

### Hearing-only, open set words in quiet

- 89% of recipients (32/36) demonstrated significant improvement in the recognition of open set monosyllabic words using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 38.3% of the words, with a median score of 40%.

## Communication Profile for the Hearing-Impaired (CPHI) communication performance scale

The 18 item Communication Performance Scale of the CPHI was completed pre- and postoperatively by 59 of the 67 clinical trial subjects. The CPHI uses a five point rating scale to assess respondents' ability to communicate effectively in a variety of social, work-related and home settings. An improvement of one level rating is considered by the authors of the CPHI to represent a clinically significant difference. Not all of the communication environments assessed by the CPHI were experienced by all subjects. The following statements summarise self-reported changes in communication abilities as assessed by the CPHI. When using the Nucleus 24:

- Three-quarters ( 45/59; 76.3%) of the respondents reported communicating more effectively when driving in a car with family members.
- Three-quarters (40/54; 74.1%) of the respondents reported communicating more effectively when ordering in a restaurant.
- Three-quarters (42/55; 76.4%) of the respondents reported communicating more effectively at a dinner party.
- Three-quarters (36/46; 78.3%) of the respondents reported hearing religious services more effectively.
- Over three-quarters (41/48; 85.4%) of the respondents reported communicating more effectively in meetings.

## General performance questionnaire

The General Performance Questionnaire was administered pre- and postoperatively to 51 of 67 clinical trial participants. The 14 item, self-report questionnaire evaluated possible device-related benefits, such as enjoyment of music, ability to monitor individual voice quality, improvements in communication ability and general quality of life issues.

The following statements summarise these self-reported benefits. When using the Nucleus 24:

- Three-quarters (35/51; 69%) of the respondents reported they enjoyed listening to music (at least to some degree) compared to one-third of the respondents (15/51; 29%) preoperatively.
- Two-thirds (32/51; 63%) of the respondents recognised (at least occasionally) songs and tunes that were familiar to them before losing their hearing, compared to 35% (18/51) preoperatively.
- Over one-third (20/51; 39%) of the respondents recognised familiar songs and tunes at least half of the time.
- 86% of the respondents (44/51) reported they could frequently or almost always monitor the loudness and quality of their voice compared to only 35% (18/51) preoperatively.
- 90% (46/51) of the respondents reported an overall improvement in communication ability without lipreading.

## Regarding general quality of life issues

- 88% (45/51) of the respondents indicated that they were satisfied with the cochlear implant system after three months of experience.
- 92% (47/51) of the respondents were happy they made the decision to undergo surgery and receive the implant.
- 92% (47/51) of the respondents indicated that the quality of their lives improved after receiving the Nucleus 24.

# Nucleus 24 and advanced speech processing strategies

The effectiveness of three advanced speech processing strategies, CIS, SPEAK, and ACE™, was assessed in a sample of 51 postlinguistically deafened adults. Prior to the study, all participants had at least three months of experience with the Nucleus 24 cochlear implant, using the SPEAK speech processing strategy. Study participants represented a broad range of postoperative outcomes and were randomly assigned to one of two experimental groups. Following a baseline performance evaluation using SPEAK, 27 subjects assigned to Group A were fitted with an optimised CIS strategy, and 24 subjects assigned to Group B were fitted with an optimised ACE strategy. After six weeks of experience with CIS (Group A) or ACE (Group B), each subject's performance was re-evaluated and compared to his or her SPEAK baseline, using a binomial statistical model. Tests of open set speech recognition included CNC Monosyllabic Words, CUNY Sentences, and HINT Sentences administered in quiet. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). A comparative questionnaire was administered to each subject at the six week interval, to evaluate strategy preferences in a variety of listening environments.

## Matrix of CIS and ACE™ programming parameters

As shown in the following matrix, the 51 investigational subjects and their audiologists selected different combinations of CIS and ACE programming parameters as optimal. For each participant, the optimal stimulation rate (per channel) is displayed along the x-axis and the optimal number of stimulation sites (channels for CIS and maxima for ACE) is displayed along the y-axis.

As illustrated, study participants selected:

- A wide range of CIS and ACE programming parameters
- Optimal stimulation rates ranging from 720 Hz – 2400 Hz per channel
- Optimal total stimulation rates ranging from 5,760 Hz – 14,400 Hz
- A minimum of six and up to 20 channels (CIS) or maxima (ACE) of stimulation, as optimal.

The broad range of CIS and ACE programming parameters selected by study participants demonstrates the inherent flexibility of the Nucleus 24 system.

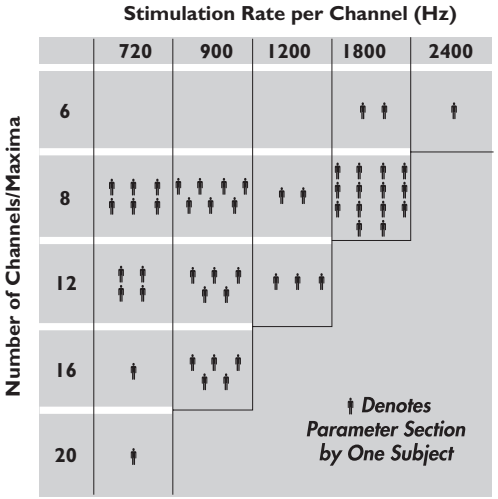


Figure 1: Distribution of CIS and ACE programming parameters for 51 investigational subjects

## Speech perception results for Groups A and B

The 27 adults who converted from the baseline SPEAK strategy to CIS (Group A) recognised an average of:

- 78% of words in open set CUNY Sentences when using SPEAK, compared to 74% when using CIS. Median open set scores for the two strategies were 91% and 92%, respectively.
- 63% of words in open set HINT Sentences when using SPEAK, compared to 61% when using CIS. Median scores were 74% for both SPEAK and CIS.
- 65% of words in CUNY Sentences in the presence of background noise using SPEAK, and 63% with CIS. Median noise scores were 77% and 74%, respectively.
- 39% of monosyllabic words with SPEAK and 35% with CIS. Median open set word recognition scores were 40% (SPEAK) and 42% (CIS).

The 24 adults who converted from the baseline SPEAK strategy to ACE (Group B) recognised an average of:

- 80% of words in CUNY Sentences when using SPEAK, compared to 81% when using ACE. For both strategies, median open set scores were 92%.
- 65% of words in open set HINT Sentences when using SPEAK, compared to 66% with ACE. Median scores were 68% and 66% for SPEAK and ACE, respectively.
- 63% of words in CUNY Sentences in the presence of background noise using SPEAK, and 67% with ACE. Median noise scores were 65% for SPEAK and 74% for ACE.
- 42% of open set CNC Words with SPEAK, and 41% of the words with ACE. Median scores were 37% (SPEAK) and 35% (ACE).

## Speech perception results for individual subjects

- No single speech processing strategy provided optimal performance for all study participants. When evaluated with CUNY Sentences presented in background noise, ten of the 27 subjects (37%) who tried SPEAK and CIS performed best with SPEAK, eight (30%) with CIS, and nine (33%) performed equally well with both strategies. Of the 24 subjects who tried SPEAK and ACE, seven (29%) performed best with SPEAK, nine (38%) with ACE, and eight (33%) performed equally well with both strategies.
- Postlinguistically deafened adult cochlear implant recipients derived significant benefit from access to multiple speech processing strategies and a broad choice of implementation options.

## Questionnaire results

Following six weeks of experience with the new speech processing strategy, a questionnaire was administered to 49 of the 51 study participants. Respondents rated the ease with which they adjusted to the new strategy and also expressed relative preferences for one of the two strategies in a variety of listening environments. For preference-related items, participants were asked to indicate whether they (1) preferred SPEAK, (2) preferred the new strategy (i.e. CIS for Group A and ACE for Group B), (3) perceived SPEAK and the new strategy as equivalent or, (4) were not sure of their preference. The following statements summarise this self-reported information.

Of the 27 adults who converted from SPEAK to CIS:

- One-third (9/27; 33%) of the respondents rated the conversion process as 'easy'.
- Almost half (13/27; 48%) of the respondents preferred SPEAK when listening in quiet, 30% (8/27) preferred CIS, and 19% (5/27) rated the two strategies as equivalent.
- Two-thirds (18/27; 67%) of the respondents preferred SPEAK when listening in background noise, compared to 26% (7/27) who preferred CIS.
- When listening to music, 26% (7/27) and 33% (9/27) of the respondents preferred SPEAK and CIS, respectively.
- When using the telephone, 41% (11/27) of the respondents preferred SPEAK, 7% (2/27) preferred CIS, and 26% (7/27) rated the two strategies as equivalent.
- Over half (14/27; 52%) of the respondents selected SPEAK as their preferred strategy 'overall'.
- One-third (9/27; 33%) of the respondents selected CIS as their preferred strategy 'overall'.

Of the 24 adults who converted from SPEAK to ACE:

- Over half (13/22; 59%) of the respondents rated the conversion process as 'easy'.
- 27% (6/22) of the respondents preferred SPEAK when listening in quiet, 32% (7/22) preferred ACE, and 27% (6/22) rated the two strategies as equivalent.
- 36% (8/22) of the respondents preferred SPEAK when listening in background noise and 32% (7/22) preferred ACE.
- When listening to music, 18% (4/22) of the respondents preferred SPEAK and 18% (4/22) preferred ACE. 23% (5/22) rated the two strategies as equivalent.
- 36% (8/22) of the respondents preferred SPEAK when using the telephone. 18% (4/22) preferred ACE, and 18% (4/22) rated the two strategies as equivalent.
- Almost one-third (7/22; 32%) of the respondents selected SPEAK as their preferred 'overall' strategy.
- 23% (5/22) of the respondents selected ACE as their preferred 'overall' strategy.

After only six weeks of experience using either CIS or ACE:

- Almost three-quarters (35/49; 71%) of the respondents reported an overall preference for one strategy over the other (i.e. Group A: SPEAK or CIS, Group B: SPEAK or ACE).

# Children

Effectiveness of the Nucleus 24 system in older (five years and above) children was assessed by comparing the speech perception abilities of 23 pre- and postlinguistically deafened subjects preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after six months of device use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Recorded versions of various paediatric speech perception measures were presented at 70 dB SPL. Individual subject results were analysed using a binomial statistical model and group means were analysed using paired t-tests and the non-parametric Wilcoxon Signed Ranks tests.

Of the children five years of age and older who were capable of being tested on open set word recognition tasks:

- 61% (14/23) demonstrated significant improvement on the Glendonald Auditory Screening Procedure (GASP).
- 44% (10/23) demonstrated significant improvement on the MLNT.
- 57% (13/23) demonstrated significant improvement on the LNT.
- 48% (11/23) demonstrated significant improvement on the Phonetically-Balanced Kindergarten (PBK) monosyllabic word test.

Group mean performance was significantly higher after six months of experience with the Nucleus 24, on all 11 measures of speech perception administered to children five years of age and older. These measures ranged from simple closed-tests to more difficult open set word and sentence recognition tests.

Device effectiveness for older children also was assessed through parental ratings of their child's auditory behaviours in a variety of everyday listening situations on the Meaningful Auditory Integration Scale (MAIS). For 19 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Ratings describing the frequency of occurrence of the child's auditory behaviours ranged from 0 (Never) to 4 (Always). Results were analysed as the proportion of children rated who demonstrated the specific behaviour either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 83% (15/18) of the children frequently or always responded to their name in quiet compared with only 47% (9/19) preoperatively with hearing aids.
- 47% (9/19) of the children frequently or always responded to their name in noise compared with only 11% (2/19) preoperatively with hearing aids.
- 79% (15/19) of the children frequently or always spontaneously recognised common sounds in the classroom compared with 26% (5/19) preoperatively with hearing aids.

### Younger children (ages 18 months to 4 years, 11 months)

Effectiveness of the Nucleus 24 system in younger children was assessed in part through parental ratings of their child's auditory behaviours in a variety of everyday listening situations on the MAIS. For 22 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Ratings describing the frequency of occurrence of the child's auditory behaviours ranged from 0 (Never) to 4 (Always). Results were analysed as the proportion of children rated who demonstrated the specific behaviour either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 68% (15/22) of the children frequently or always responded to their name in quiet compared with only 27% (6/22) preoperatively with hearing aids.
- 45% (10/22) of the children frequently or always responded to their name in noise compared with only 14% (3/22) preoperatively with hearing aids.
- 41% (9/22) of the children frequently or always spontaneously recognised common sounds in the classroom compared with 14% (3/22) preoperatively with hearing aids.

## Neural Response Telemetry (NRT™)

The Neural Response Telemetry (NRT™) system of the Nucleus 24 is capable of detecting physiological responses of elements of the auditory nerve within the cochlea.

# Clinical considerations

Adult and pediatric patients deafened from birth to two years of age are considered to be prelinguistically deafened, while those with an onset of deafness from two to five years of age are considered to be perilinguistically deafened. Postlinguistically deafened patients typically are deafened after the age of five and present with age-appropriate speech and language skills.

Optimised hearing aid fitting and evaluation procedures are critical to the selection of suitable cochlear implant candidates. In order to ensure selection of appropriate candidates, hearing healthcare professionals should utilise state of the art amplification and diagnostic instruments, and clinically accepted hearing aid evaluation and fitting procedures.

Adults with severe to profound, postlinguistic, sensorineural hearing loss commonly present with asymmetrical audiometric profiles. When clinically appropriate, it is recommended that the poorer ear be selected for implantation, as surgical placement of the device will result in complete loss of residual hearing in the implanted ear. When selecting the ear for implantation, open set sentence recognition scores with hearing aids should be considered over more conventional audiological measures, as appropriate clinical indicators of preoperative auditory function.

Prelinguistically and perilinguistically deafened adults who do not have functional oral speech and language skills, and who are not highly motivated to participate in the rehabilitation process, are more likely to become non users of the device than are other adult patients. Prospective patients and their families should be counseled extensively regarding the limited nature of expected postoperative benefits, and should understand that prelinguistically and perilinguistically deafened adults are at risk for device non use.

Many prelinguistically and perilinguistically deafened adults demonstrate improved detection of medium to loud environmental sounds, including speech. A few individuals demonstrate improved lipreading abilities, following extensive rehabilitation. (Average test scores improved by less than 10%, when the device was used in conjunction with lipreading.)

There was no significant difference in performance between the SPrint (body worn) and the ESPrit (ear level) processors on any measure of open set speech perception in quiet or in noise.

# Other information

## Patient counselling

### Preoperative counselling

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

## Storage, handling and sterilisation

Implants should be stored at normal room temperature. Implants may be stored at temperatures between -4 °F and +120 °F (-20 °C and +50 °C). The 'use by' date is stamped on the outside package. If it has expired, return the device to Cochlear.

Handle the implant packages with care. Severe impact may rupture the inner sterile package.

Cochlear implants are supplied sterile in gas-permeable packaging. The titanium plugs and replacement magnets are supplied separately in sterile gas-permeable packaging. These are single use items. The sterile package contains information indicating ethylene oxide processing. Before opening the sterile package, inspect it carefully. If the package is ruptured, or exposure to ethylene oxide processing is not indicated, please return the package to Cochlear.

# Information for use and recommended training

Physicians should be very experienced in mastoid surgery and the facial recess approach to the round window. It is important that physicians be trained in the implantation procedure for the CI500 Series and Nucleus 24. It is strongly recommended that the surgeon work with an experienced team of audiology, speech-language, rehabilitation, education and psychology professionals. It is recommended that audiology professionals attend a training program for this device. Cochlear Americas conducts periodic training courses.

For product-specific information, refer to the Surgeon's Guide supplied with each implant.

# Notes

# Notes

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Cochlear™

# Nucleus® CI422 cochlear implant

Physician's Package Insert

Hear now. And always

Cochlear®

## Symbols

**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.

This document contains important information such as indications and contraindications that apply to the Cochlear™ Nucleus® cochlear implant system.

# Contents

# Notes

# Device description

Cochlear Nucleus implant systems are designed to provide useful hearing. The system works by converting sound in the environment into electrical code. It transmits this code to the auditory nerve and on to the brain where it is interpreted as sound.

The Cochlear Nucleus 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 and an electrode array to deliver these signals to the cochlea.

## External components

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

The system is programmed by a Cochlear proprietary programming system.

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

# Indications

The cochlear implant is intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve.

## Adults

Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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 tape-recorded tests of open set sentence recognition.

## Children

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test. In older children, limited benefit is defined as ≤ 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.

# Contraindications

A cochlear implant is not indicated for individuals who have the following conditions:

- Deafness due to lesions of the acoustic nerve or central auditory pathway
- Active middle ear infections
- Absence of cochlear development
- Tympanic membrane perforation in the presence of active middle ear disease.

# ⚠ Warnings

## Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Before initiating any of the following treatments deactivate the device.

Warnings for specific treatments are provided below.

### Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in.) from the extracochlear electrodes.

### Diathermy

Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

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

### Neurostimulation

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

### Electroconvulsive therapy

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

### Ionizing radiation therapy

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

## Pediatrics

To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist should be present during surgery for infants implanted under 12 months of age.

# MRI safety information


The Cochlear Nucleus CI422 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.


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

## Meningitis

Prior to 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.

In addition, certain preoperative conditions may increase the risk of meningitis with or without a cochlear implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

## Loss of residual hearing

Insertion of the electrode into the cochlea will result in complete loss of residual hearing in the implanted ear.

## Long-term effects of electrical stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

## Small parts hazard

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

## Battery ingestion

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If swallowed, seek prompt medical attention at the nearest emergency center

## Head trauma

A blow to the head in the area of the cochlear implant may damage the implant and result in its failure. Young children who are developing their motor skills are at greater risk to receive an impact to the head from a hard object (e.g. a table or chair).

Impact to external components (e.g. sound processor, acoustic component) while being worn could result in damage to the device or injury.

## Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort. Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears). The rechargeable battery should not be used by patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

# ⚠ Precautions

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

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

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

Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user. If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left, and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

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

Do not store the processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).

Your processor's sound quality may be intermittently distorted when you are within approximately 1.6 km (~1 mile) of a radio or television transmission tower. Additional sources of interference include, but are not limited to:

- Security systems
- Industrial machinery and power systems
- Mobile communications equipment (including cellular telephones)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

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

## Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off your processor when in the vicinity of one of these devices.

The materials used in the cochlear implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

## Electrostatic discharge (ESD)

A discharge of static electricity can in rare cases damage the electrical components of the cochlear implant system or corrupt the program in your processor.

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

Prior to engaging in activities that create extreme electrostatic discharge (ESD), such as playing on plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

## Mobile telephones

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

# Adverse events

The following information summarises adverse events for adults and children implanted with the Nucleus 24 cochlear implant.

## Adults

Adult safety data are based on a total of 133 patients implanted with the Nucleus 24 during the adult clinical investigation at 27 U.S. sites. 20 patients experienced either a medical/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

# Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

## Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

## Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

## Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

# Results of clinical studies

The clinical study results contained in the Physician's Package Insert reflect clinical trials conducted with the Nucleus 24 straight array.

## Adults

### SPrint™ (body worn) processor

Effectiveness of the Nucleus 24 system using the SPrint body worn processor was assessed by comparing the speech perception abilities of 67 postlinguistically deafened adults preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after three months of device use. Postoperatively, the body worn SPrint processor was programmed to implement the Spectral-peak (SPEAK) speech processing strategy. Recorded measures of open set sentence recognition were presented in quiet using City University of New York (CUNY) and Hearing in Noise Test (HINT) Sentences. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). Open set speech recognition was also assessed over long-distance telephone lines using Central Institute for the Deaf (CID) Everyday Sentences of Speech Test and the Psycho-Acoustic Laboratory Sentences (PAL). Recorded measures of open set, monosyllabic word recognition (Consonant-Nucleus-Consonant (CNC) Words) were presented in quiet. Due to the high levels of performance exhibited by adults using the Nucleus 24, more simple measures of lipreading enhancement and closed set speech perception were not included in the evaluation battery. Individual subject results were analysed using a binomial statistical model.

### Hearing-only, open set sentences in quiet

- After three months of experience with the Nucleus 24, almost all recipients (66/67; 98.5%) demonstrated significant improvement in open set sentence recognition (CUNY) compared to their preoperative performance with hearing aids. All individuals demonstrated significantly above-chance sentence recognition. Recipients recognised an average of 78% of words in sentences, with a median score of 87%. Approximately half of the recipients (49.3%) recognised 90% or more words and approximately two-thirds (62.7%) recognised 80% or more words.
- Recipients rapidly developed high levels of open set speech perception after limited experience with the Nucleus 24. Average sentence recognition (CUNY) increased from 56% to 65% to 78% and median scores increased from 58% to 72% to 87% after two weeks, one month and three months of device use, respectively. After only two weeks, approximately one-third (31.3%) of the recipients recognised 80% or more words. After only one month, approximately half (47.8%) of the recipients recognised 75% or more words.
- After three months of experience with the Nucleus 24, almost all recipients (63/67; 94.0%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) compared to their preoperative performance with hearing aids. Almost all individuals demonstrated significantly above-chance speech recognition. Recipients recognised an average of 60% of the words in these more difficult sentences, with a median score of 63%. Approximately one-third of the recipients (35.8%) recognised 75% or more words.

### Hearing-only, open set sentences in noise (+10 dB Signal-to-Noise Ratio (SNR))

After three months of experience with the Nucleus 24:

- Almost all recipients (61/66; 92.4%) demonstrated significant improvement in the recognition of recorded, open set sentences (CUNY) in the presence of background noise, compared to their preoperative performance with hearing aids. All but one recipient demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' listening situations (background noise), recipients recognised an average of 59% of the words, with a median score of 67%. One-third of the recipients (36.3%) recognised 75% or more words and approximately one-half of the recipients (47.0%) recognised 70% or more words.

### Hearing-only, open set words in quiet

After three months of experience with the Nucleus 24:

- 88% of recipients (59/67) demonstrated significant improvement in the recognition of recorded, open set monosyllabic words compared to their preoperative performance with hearing aids. Monosyllabic word recognition ranged from 0% to 80%.
- Recipients recognised an average of 37% of the words, with a median score of 36%. 18% of the recipients (12/67) recognised 60% or more words and 28% of recipients (19/67) recognised 50% or more words.

## Telephone testing

All telephone testing was administered over long-distance telephone lines using recorded, open set sentence measures (CID and PAL sentences). Under these difficult listening conditions, after three months of experience with the Nucleus 24:

- 91% of the recipients (61/67) demonstrated significant improvement in the recognition of open set sentences (CID) compared to their preoperative performance with hearing aids. Almost all recipients (65/67; 97%) recognised these sentences at significantly above-chance levels. 79% (53/67) demonstrated significant improvement in the comprehension of open set sentences (PAL) compared to their preoperative performance with hearing aids.
- Recipients scored an average of 60% and 58% on CID and PAL Sentences, with median scores of 66% and 65%, respectively. Approximately half of the recipients (47.8%) recognised 70% or more of recorded words in sentences (CID), and 21% of recipients recognised 90% or more words. Approximately a quarter (23.9%) of the recipients correctly answered 90% or more of recorded questions (PAL), and approximately half (50.8%) correctly answered 70% or more questions.

## ESPrit™ (ear level) processor

After a minimum of three months experience with the SPrint processor, 36 subjects were fitted with the ESPrit ear level processor (programmed to implement the SPEAK speech processing strategy) and speech perception was evaluated following one month of ESPrit use. Recorded measures of open set sentence recognition were presented in quiet and in the presence of background noise (+10 dB SNR), at a level that was moderately difficult for the typical cochlear implant recipient. Recorded measures of open set word recognition were presented in quiet. ESPrit performance was compared with each subject's preoperative baseline, as well as with the SPrint postoperative baseline. The evaluation measures for the ESPrit were the same as those used to assess the SPrint, except that telephone use with the ESPrit was not assessed. Individual subject results were analyzed using a binomial statistical model.

### Hearing-only, open set sentences in quiet

- Almost all recipients (34/36; 94.4%) demonstrated significant improvement in the recognition of open set sentences (CUNY) using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 79.6% of the words in sentences, with a median score of 91%.
- All recipients tested (35/35; 100%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 63.4% of the words, with median score of 65%.

### Hearing-only, open set sentences in noise (+10 dB SNR)

- Almost all recipients (32/36; 88.9%) demonstrated significant improvement in the recognition of open set sentences (CUNY) in the presence of background noise using the ESPrit compared to their preoperative performance with hearing aids. All but four recipients demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' situations (background noise), recipients recognised an average of 57.9% of words in sentences, with a median score of 64%.

### Hearing-only, open set words in quiet

- 89% of recipients (32/36) demonstrated significant improvement in the recognition of open set monosyllabic words using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 38.3% of the words, with a median score of 40%.

## Communication Profile for the Hearing-Impaired (CPHI) communication performance scale

The 18 item Communication Performance Scale of the CPHI was completed pre- and postoperatively by 59 of the 67 clinical trial subjects. The CPHI uses a five point rating scale to assess respondents' ability to communicate effectively in a variety of social, work-related and home settings. An improvement of one level rating is considered by the authors of the CPHI to represent a clinically significant difference. Not all of the communication environments assessed by the CPHI were experienced by all subjects. The following statements summarise self-reported changes in communication abilities as assessed by the CPHI. When using the Nucleus 24:

- Three-quarters ( 45/59; 76.3%) of the respondents reported communicating more effectively when driving in a car with family members.
- Three-quarters (40/54; 74.1%) of the respondents reported communicating more effectively when ordering in a restaurant.
- Three-quarters (42/55; 76.4%) of the respondents reported communicating more effectively at a dinner party.
- Three-quarters (36/46; 78.3%) of the respondents reported hearing religious services more effectively.
- Over three-quarters (41/48; 85.4%) of the respondents reported communicating more effectively in meetings.

## General performance questionnaire

The General Performance Questionnaire was administered pre- and postoperatively to 51 of 67 clinical trial participants. The 14 item, self-report questionnaire evaluated possible device-related benefits, such as enjoyment of music, ability to monitor individual voice quality, improvements in communication ability and general quality of life issues.

The following statements summarise these self-reported benefits. When using the Nucleus 24:

- Three-quarters (35/51; 69%) of the respondents reported they enjoyed listening to music (at least to some degree) compared to one-third of the respondents (15/51; 29%) preoperatively.
- Two-thirds (32/51; 63%) of the respondents recognised (at least occasionally) songs and tunes that were familiar to them before losing their hearing, compared to 35% (18/51) preoperatively.
- Over one-third (20/51; 39%) of the respondents recognised familiar songs and tunes at least half of the time.
- 86% of the respondents (44/51) reported they could frequently or almost always monitor the loudness and quality of their voice compared to only 35% (18/51) preoperatively.
- 90% (46/51) of the respondents reported an overall improvement in communication ability without lipreading.

## Regarding general quality of life issues

- 88% (45/51) of the respondents indicated that they were satisfied with the cochlear implant system after three months of experience.
- 92% (47/51) of the respondents were happy they made the decision to undergo surgery and receive the implant.
- 92% (47/51) of the respondents indicated that the quality of their lives improved after receiving the Nucleus 24.

# Nucleus 24 and advanced speech processing strategies

The effectiveness of three advanced speech processing strategies, CIS, SPEAK, and ACE™, was assessed in a sample of 51 postlinguistically deafened adults. Prior to the study, all participants had at least three months of experience with the Nucleus 24 cochlear implant, using the SPEAK speech processing strategy. Study participants represented a broad range of postoperative outcomes and were randomly assigned to one of two experimental groups. Following a baseline performance evaluation using SPEAK, 27 subjects assigned to Group A were fitted with an optimised CIS strategy, and 24 subjects assigned to Group B were fitted with an optimised ACE strategy. After six weeks of experience with CIS (Group A) or ACE (Group B), each subject's performance was re-evaluated and compared to his or her SPEAK baseline, using a binomial statistical model. Tests of open set speech recognition included CNC Monosyllabic Words, CUNY Sentences, and HINT Sentences administered in quiet. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). A comparative questionnaire was administered to each subject at the six week interval, to evaluate strategy preferences in a variety of listening environments.

## Matrix of CIS and ACE™ programming parameters

As shown in the following matrix, the 51 investigational subjects and their audiologists selected different combinations of CIS and ACE programming parameters as optimal. For each participant, the optimal stimulation rate (per channel) is displayed along the x-axis and the optimal number of stimulation sites (channels for CIS and maxima for ACE) is displayed along the y-axis.

As illustrated, study participants selected:

- A wide range of CIS and ACE programming parameters
- Optimal stimulation rates ranging from 720 Hz – 2400 Hz per channel
- Optimal total stimulation rates ranging from 5,760 Hz – 14,400 Hz
- A minimum of six and up to 20 channels (CIS) or maxima (ACE) of stimulation, as optimal.

The broad range of CIS and ACE programming parameters selected by study participants demonstrates the inherent flexibility of the Nucleus 24 system.

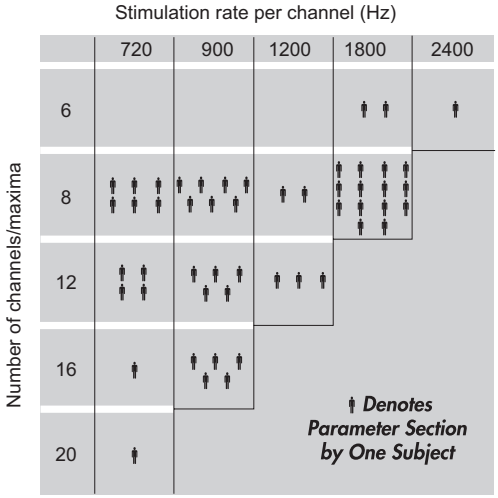


Figure 1: Distribution of CIS and ACE programming parameters for 51 investigational subjects

## Speech perception results for Groups A and B

The 27 adults who converted from the baseline SPEAK strategy to CIS (Group A) recognised an average of:

- 78% of words in open set CUNY Sentences when using SPEAK, compared to 74% when using CIS. Median open set scores for the two strategies were 91% and 92%, respectively.
- 63% of words in open set HINT Sentences when using SPEAK, compared to 61% when using CIS. Median scores were 74% for both SPEAK and CIS.
- 65% of words in CUNY Sentences in the presence of background noise using SPEAK, and 63% with CIS. Median noise scores were 77% and 74%, respectively.
- 39% of monosyllabic words with SPEAK and 35% with CIS. Median open set word recognition scores were 40% (SPEAK) and 42% (CIS).

The 24 adults who converted from the baseline SPEAK strategy to ACE (Group B) recognised an average of:

- 80% of words in CUNY Sentences when using SPEAK, compared to 81% when using ACE. For both strategies, median open set scores were 92%.
- 65% of words in open set HINT Sentences when using SPEAK, compared to 66% with ACE. Median scores were 68% and 66% for SPEAK and ACE, respectively.
- 63% of words in CUNY Sentences in the presence of background noise using SPEAK, and 67% with ACE. Median noise scores were 65% for SPEAK and 74% for ACE.
- 42% of open set CNC Words with SPEAK, and 41% of the words with ACE. Median scores were 37% (SPEAK) and 35% (ACE).

## Speech perception results for individual subjects

- No single speech processing strategy provided optimal performance for all study participants. When evaluated with CUNY Sentences presented in background noise, ten of the 27 subjects (37%) who tried SPEAK and CIS performed best with SPEAK, eight (30%) with CIS, and nine (33%) performed equally well with both strategies. Of the 24 subjects who tried SPEAK and ACE, seven (29%) performed best with SPEAK, nine (38%) with ACE, and eight (33%) performed equally well with both strategies.
- Postlinguistically deafened adult cochlear implant recipients derived significant benefit from access to multiple speech processing strategies and a broad choice of implementation options.

## Questionnaire results

Following six weeks of experience with the new speech processing strategy, a questionnaire was administered to 49 of the 51 study participants. Respondents rated the ease with which they adjusted to the new strategy and also expressed relative preferences for one of the two strategies in a variety of listening environments. For preference-related items, participants were asked to indicate whether they (1) preferred SPEAK, (2) preferred the new strategy (i.e. CIS for Group A and ACE for Group B), (3) perceived SPEAK and the new strategy as equivalent or, (4) were not sure of their preference. The following statements summarise this self-reported information.

Of the 27 adults who converted from SPEAK to CIS:

- One-third (9/27; 33%) of the respondents rated the conversion process as 'easy'.
- Almost half (13/27; 48%) of the respondents preferred SPEAK when listening in quiet, 30% (8/27) preferred CIS, and 19% (5/27) rated the two strategies as equivalent.
- Two-thirds (18/27; 67%) of the respondents preferred SPEAK when listening in background noise, compared to 26% (7/27) who preferred CIS.
- When listening to music, 26% (7/27) and 33% (9/27) of the respondents preferred SPEAK and CIS, respectively.
- When using the telephone, 41% (11/27) of the respondents preferred SPEAK, 7% (2/27) preferred CIS, and 26% (7/27) rated the two strategies as equivalent.
- Over half (14/27; 52%) of the respondents selected SPEAK as their preferred strategy 'overall'.
- One-third (9/27; 33%) of the respondents selected CIS as their preferred strategy 'overall'.

Of the 24 adults who converted from SPEAK to ACE:

- Over half (13/22; 59%) of the respondents rated the conversion process as 'easy'.
- 27% (6/22) of the respondents preferred SPEAK when listening in quiet, 32% (7/22) preferred ACE, and 27% (6/22) rated the two strategies as equivalent.
- 36% (8/22) of the respondents preferred SPEAK when listening in background noise and 32% (7/22) preferred ACE.
- When listening to music, 18% (4/22) of the respondents preferred SPEAK and 18% (4/22) preferred ACE. 23% (5/22) rated the two strategies as equivalent.
- 36% (8/22) of the respondents preferred SPEAK when using the telephone. 18% (4/22) preferred ACE, and 18% (4/22) rated the two strategies as equivalent.
- Almost one-third (7/22; 32%) of the respondents selected SPEAK as their preferred 'overall' strategy.
- 23% (5/22) of the respondents selected ACE as their preferred 'overall' strategy.

After only six weeks of experience using either CIS or ACE:

- Almost three-quarters (35/49; 71%) of the respondents reported an overall preference for one strategy over the other (i.e. Group A: SPEAK or CIS, Group B: SPEAK or ACE).

# Children

Effectiveness of the Nucleus 24 system in older (five years and above) children was assessed by comparing the speech perception abilities of 23 pre- and postlinguistically deafened subjects preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after six months of device use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Recorded versions of various pediatric speech perception measures were presented at 70 dB SPL. Individual subject results were analyzed using a binomial statistical model and group means were analyzed using paired t-tests and the non-parametric Wilcoxon Signed Ranks tests.

Of the children five years of age and older who were capable of being tested on open set word recognition tasks:

- 61% (14/23) demonstrated significant improvement on the Glendonald Auditory Screening Procedure (GASP).
- 44% (10/23) demonstrated significant improvement on the MLNT.
- 57% (13/23) demonstrated significant improvement on the LNT.
- 48% (11/23) demonstrated significant improvement on the Phonetically-Balanced Kindergarten (PBK) monosyllabic word test.

Group mean performance was significantly higher after six months of experience with the Nucleus 24, on all 11 measures of speech perception administered to children five years of age and older. These measures ranged from simple closed-tests to more difficult open set word and sentence recognition tests.

Device effectiveness for older children also was assessed through parental ratings of their child's auditory behaviours in a variety of everyday listening situations on the Meaningful Auditory Integration Scale (MAIS). For 19 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Ratings describing the frequency of occurrence of the child's auditory behaviours ranged from 0 (Never) to 4 (Always). Results were analyzed as the proportion of children rated who demonstrated the specific behaviour either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 83% (15/18) of the children frequently or always responded to their name in quiet compared with only 47% (9/19) preoperatively with hearing aids.
- 47% (9/19) of the children frequently or always responded to their name in noise compared with only 11% (2/19) preoperatively with hearing aids.
- 79% (15/19) of the children frequently or always spontaneously recognised common sounds in the classroom compared with 26% (5/19) preoperatively with hearing aids.

### Younger children (ages 18 months to 4 years, 11 months)

Effectiveness of the Nucleus 24 system in younger children was assessed in part through parental ratings of their child's auditory behaviours in a variety of everyday listening situations on the MAIS. For 22 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Ratings describing the frequency of occurrence of the child's auditory behaviours ranged from 0 (Never) to 4 (Always). Results were analyzed as the proportion of children rated who demonstrated the specific behaviour either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 68% (15/22) of the children frequently or always responded to their name in quiet compared with only 27% (6/22) preoperatively with hearing aids.
- 45% (10/22) of the children frequently or always responded to their name in noise compared with only 14% (3/22) preoperatively with hearing aids.
- 41% (9/22) of the children frequently or always spontaneously recognised common sounds in the classroom compared with 14% (3/22) preoperatively with hearing aids.

## Neural Response Telemetry (NRT™)

The Neural Response Telemetry (NRT™) system of the Cochlear Nucleus CI422 cochlear implant is capable of detecting physiological responses of elements of the auditory nerve within the cochlea.

# Clinical considerations

Adult and pediatric patients deafened from birth to two years of age are considered to be prelinguistically deafened, while those with an onset of deafness from two to five years of age are considered to be perilinguistically deafened. Postlinguistically deafened patients typically are deafened after the age of five and present with age-appropriate speech and language skills.

Optimised hearing aid fitting and evaluation procedures are critical to the selection of suitable cochlear implant candidates. In order to ensure selection of appropriate candidates, hearing healthcare professionals should utilise state of the art amplification and diagnostic instruments, and clinically accepted hearing aid evaluation and fitting procedures.

Adults with severe to profound, postlinguistic, sensorineural hearing loss commonly present with asymmetrical audiometric profiles. When clinically appropriate, it is recommended that the poorer ear be selected for implantation, as surgical placement of the device will result in complete loss of residual hearing in the implanted ear. When selecting the ear for implantation, open set sentence recognition scores with hearing aids should be considered over more conventional audiological measures, as appropriate clinical indicators of preoperative auditory function.

Prelinguistically and perilinguistically deafened adults who do not have functional oral speech and language skills, and who are not highly motivated to participate in the rehabilitation process, are more likely to become non users of the device than are other adult patients. Prospective patients and their families should be counseled extensively regarding the limited nature of expected postoperative benefits, and should understand that prelinguistically and perilinguistically deafened adults are at risk for device non use.

Many prelinguistically and perilinguistically deafened adults demonstrate improved detection of medium to loud environmental sounds, including speech. A few individuals demonstrate improved lipreading abilities, following extensive rehabilitation. (Average test scores improved by less than 10%, when the device was used in conjunction with lipreading.)

There was no significant difference in performance between the SPrint (body worn) and the ESPrit (ear level) processors on any measure of open set speech perception in quiet or in noise.

# Other information

## Patient counselling

### Preoperative counselling

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

## Storage, handling and sterilisation

Transport and store Nucleus implants at temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

For long term storage, store at ambient room temperature. Keep dry.

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

The implant, non-magnetic plugs and replacement magnets are single-use items. The non-magnetic plugs and replacement magnets are supplied separately.

All of the above components are supplied in sterile packaging. Ethylene oxide processing is indicated by a green dot 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 pack containing the implant is ruptured
- exposure to ethylene oxide processing is not indicated.

# Information for use and recommended training

Physicians should be very experienced in mastoid surgery and the facial recess approach to the round window. It is important that physicians be trained in the implantation procedure for the CI500 Series and Nucleus 24. It is strongly recommended that the surgeon work with an experienced team of audiology, speech-language, rehabilitation, education and psychology professionals. It is recommended that audiology professionals attend a training program for this device. Cochlear Americas conducts periodic training courses.

For product-specific information, refer to the Surgeon's Guide supplied with each implant.

# Notes

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## www.cochlear.com



*Hear now. And always*

249169 ISS6 FEB20

Cochlear™

# Nucleus® CI512 cochlear implant

Physician's Package Insert

Hear now. And always

Cochlear®

## Symbols

**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.

This document contains important information such as indications and contraindications that apply to the Cochlear™ Nucleus® cochlear implant system.

# Contents

# Notes

# Device description

Cochlear Nucleus implant systems are designed to provide useful hearing. The system works by converting sound in the environment into electrical code. It transmits this code to the auditory nerve and on to the brain where it is interpreted as sound.

The Cochlear Nucleus 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 and an electrode array to deliver these signals to the cochlea.

## External components

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

The system is programmed by a Cochlear proprietary programming system.

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

# Intended use

The Cochlear Nucleus CI512 cochlear implant is a prescription-only, single use (non-resterilizable) device intended for chronic implantation under the skin in the mastoid region either side of the head.

# Indications

The cochlear implant is intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve.

## Adults

Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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 tape-recorded tests of open set sentence recognition.

## Children

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test. In older children, limited benefit is defined as ≤ 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.

# Contraindications

A cochlear implant is not indicated for individuals who have the following conditions:

- Deafness due to lesions of the acoustic nerve or central auditory pathway
- Active middle ear infections
- Absence of cochlear development
- Tympanic membrane perforation in the presence of active middle ear disease.

# ⚠ Warnings

## Medical treatments generating induced currents, heat or vibration

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Before initiating any of the following treatments deactivate the device.

Warnings for specific treatments are provided below.

### Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in.) from the extracochlear electrodes.

### Diathermy

Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

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

### Neurostimulation

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

### Electroconvulsive therapy

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

### Ionizing radiation therapy

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

### Therapeutic ultrasound

Do not use therapeutic levels of ultrasound energy directly over the implant. It may inadvertently concentrate the ultrasound field and cause tissue damage or damage to the implant.

## Pediatrics

To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist should be present during surgery for infants implanted under 12 months of age.

# MRI safety information


The Cochlear Nucleus CI512 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.


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

## Meningitis

Prior to 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.

In addition, certain preoperative conditions may increase the risk of meningitis with or without a cochlear implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

## Adverse environments

The operation of the cochlear implant system may be adversely affected in environments of high magnetic field strength and high electric field strengths (e.g. close to high power commercial radio transmitters).

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

## Loss of residual hearing

Insertion of the electrode into the cochlea will result in complete loss of residual hearing in the implanted ear.

## Long-term effects of electrical stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

## Small parts hazard

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

## Head trauma

A blow to the head in the area of the cochlear implant may damage the implant and result in its failure. Young children who are developing their motor skills are at greater risk to receive an impact to the head from a hard object (e.g. a table or chair).

Impact to external components (e.g. sound processor, acoustic component) while being worn could result in damage to the device or injury.

## Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort. Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears). The rechargeable battery should not be used by patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

## Overheating

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

The manufacturer only recommends the use of zinc air batteries as they have been determined to be safe in recommended use conditions and provide an appropriate power source for the sound processor.

The CP810 and CP900 Series sound processors are not intended to be used with silver oxide batteries. In some circumstances, the use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device. In addition, use of silver oxide batteries may damage your processor.

# ⚠ Precautions

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

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

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

Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user. If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left, and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

Do not operate or store your processor at temperatures other than those recommended in the user instructions supplied with your processor.

Your processor's sound quality may be intermittently distorted when you are within approximately 1.6 km (~1 mile) of a radio or television transmission tower. Additional sources of interference include, but are not limited to:

- Security systems
- Industrial machinery and power systems
- Mobile communications equipment (including cellular telephones)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

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

## Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off your processor when in the vicinity of one of these devices.

The materials used in the cochlear implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

## Electrostatic discharge (ESD)

A discharge of static electricity can in rare cases damage the electrical components of the cochlear implant system or corrupt the program in your processor.

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

Prior to engaging in activities that create extreme electrostatic discharge (ESD), such as playing on plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

## Mobile telephones

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

# Adverse events

The following information summarises adverse events for adults and children implanted with the Nucleus 24 cochlear implant.

## Adults

Adult safety data are based on a total of 133 patients implanted with the Nucleus 24 during the adult clinical investigation at 27 U.S. sites. 20 patients experienced either a medical/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

# Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

## Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

## Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

## Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

# Results of clinical studies

The clinical study results contained in the Physician's Package Insert reflect clinical trials conducted with the Nucleus 24 straight array.

## Adults

### SPrint™ (body worn) processor

Effectiveness of the Nucleus 24 system using the SPrint body worn processor was assessed by comparing the speech perception abilities of 67 postlinguistically deafened adults preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after three months of device use. Postoperatively, the body worn SPrint processor was programmed to implement the Spectral-peak (SPEAK) speech processing strategy. Recorded measures of open set sentence recognition were presented in quiet using City University of New York (CUNY) and Hearing in Noise Test (HINT) Sentences. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). Open set speech recognition was also assessed over long-distance telephone lines using Central Institute for the Deaf (CID) Everyday Sentences of Speech Test and the Psycho-Acoustic Laboratory Sentences (PAL). Recorded measures of open set, monosyllabic word recognition (Consonant-Nucleus-Consonant (CNC) Words) were presented in quiet. Due to the high levels of performance exhibited by adults using the Nucleus 24, more simple measures of lipreading enhancement and closed set speech perception were not included in the evaluation battery. Individual subject results were analysed using a binomial statistical model.

### Hearing-only, open set sentences in quiet

- After three months of experience with the Nucleus 24, almost all recipients (66/67; 98.5%) demonstrated significant improvement in open set sentence recognition (CUNY) compared to their preoperative performance with hearing aids. All individuals demonstrated significantly above-chance sentence recognition. Recipients recognised an average of 78% of words in sentences, with a median score of 87%. Approximately half of the recipients (49.3%) recognised 90% or more words and approximately two-thirds (62.7%) recognised 80% or more words.
- Recipients rapidly developed high levels of open set speech perception after limited experience with the Nucleus 24. Average sentence recognition (CUNY) increased from 56% to 65% to 78% and median scores increased from 58% to 72% to 87% after two weeks, one month and three months of device use, respectively. After only two weeks, approximately one-third (31.3%) of the recipients recognised 80% or more words. After only one month, approximately half (47.8%) of the recipients recognised 75% or more words.
- After three months of experience with the Nucleus 24, almost all recipients (63/67; 94.0%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) compared to their preoperative performance with hearing aids. Almost all individuals demonstrated significantly above-chance speech recognition. Recipients recognised an average of 60% of the words in these more difficult sentences, with a median score of 63%. Approximately one-third of the recipients (35.8%) recognised 75% or more words.

### Hearing-only, open set sentences in noise (+10 dB Signal-to-Noise Ratio (SNR))

After three months of experience with the Nucleus 24:

- Almost all recipients (61/66; 92.4%) demonstrated significant improvement in the recognition of recorded, open set sentences (CUNY) in the presence of background noise, compared to their preoperative performance with hearing aids. All but one recipient demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' listening situations (background noise), recipients recognised an average of 59% of the words, with a median score of 67%. One-third of the recipients (36.3%) recognised 75% or more words and approximately one-half of the recipients (47.0%) recognised 70% or more words.

### Hearing-only, open set words in quiet

After three months of experience with the Nucleus 24:

- 88% of recipients (59/67) demonstrated significant improvement in the recognition of recorded, open set monosyllabic words compared to their preoperative performance with hearing aids. Monosyllabic word recognition ranged from 0% to 80%.
- Recipients recognised an average of 37% of the words, with a median score of 36%. 18% of the recipients (12/67) recognised 60% or more words and 28% of recipients (19/67) recognised 50% or more words.

## Telephone testing

All telephone testing was administered over long-distance telephone lines using recorded, open set sentence measures (CID and PAL sentences). Under these difficult listening conditions, after three months of experience with the Nucleus 24:

- 91% of the recipients (61/67) demonstrated significant improvement in the recognition of open set sentences (CID) compared to their preoperative performance with hearing aids. Almost all recipients (65/67; 97%) recognised these sentences at significantly above-chance levels. 79% (53/67) demonstrated significant improvement in the comprehension of open set sentences (PAL) compared to their preoperative performance with hearing aids.
- Recipients scored an average of 60% and 58% on CID and PAL Sentences, with median scores of 66% and 65%, respectively. Approximately half of the recipients (47.8%) recognised 70% or more of recorded words in sentences (CID), and 21% of recipients recognised 90% or more words. Approximately a quarter (23.9%) of the recipients correctly answered 90% or more of recorded questions (PAL), and approximately half (50.8%) correctly answered 70% or more questions.

## ESPrit™ (ear level) processor

After a minimum of three months experience with the SPrint processor, 36 subjects were fitted with the ESPrit ear level processor (programmed to implement the SPEAK speech processing strategy) and speech perception was evaluated following one month of ESPrit use. Recorded measures of open set sentence recognition were presented in quiet and in the presence of background noise (+10 dB SNR), at a level that was moderately difficult for the typical cochlear implant recipient. Recorded measures of open set word recognition were presented in quiet. ESPrit performance was compared with each subject's preoperative baseline, as well as with the SPrint postoperative baseline. The evaluation measures for the ESPrit were the same as those used to assess the SPrint, except that telephone use with the ESPrit was not assessed. Individual subject results were analyzed using a binomial statistical model.

### Hearing-only, open set sentences in quiet

- Almost all recipients (34/36; 94.4%) demonstrated significant improvement in the recognition of open set sentences (CUNY) using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 79.6% of the words in sentences, with a median score of 91%.
- All recipients tested (35/35; 100%) demonstrated significant improvement in the recognition of more difficult open set sentences (HINT) using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 63.4% of the words, with median score of 65%.

### Hearing-only, open set sentences in noise (+10 dB SNR)

- Almost all recipients (32/36; 88.9%) demonstrated significant improvement in the recognition of open set sentences (CUNY) in the presence of background noise using the ESPrit compared to their preoperative performance with hearing aids. All but four recipients demonstrated significantly above-chance speech recognition.
- When tested in an environment designed to represent 'real world' situations (background noise), recipients recognised an average of 57.9% of words in sentences, with a median score of 64%.

### Hearing-only, open set words in quiet

- 89% of recipients (32/36) demonstrated significant improvement in the recognition of open set monosyllabic words using the ESPrit compared to their preoperative performance with hearing aids. Recipients recognised an average of 38.3% of the words, with a median score of 40%.

## Communication Profile for the Hearing-Impaired (CPHI) communication performance scale

The 18 item Communication Performance Scale of the CPHI was completed pre- and postoperatively by 59 of the 67 clinical trial subjects. The CPHI uses a five point rating scale to assess respondents' ability to communicate effectively in a variety of social, work-related and home settings. An improvement of one level rating is considered by the authors of the CPHI to represent a clinically significant difference. Not all of the communication environments assessed by the CPHI were experienced by all subjects. The following statements summarise self-reported changes in communication abilities as assessed by the CPHI. When using the Nucleus 24:

- Three-quarters ( 45/59; 76.3%) of the respondents reported communicating more effectively when driving in a car with family members.
- Three-quarters (40/54; 74.1%) of the respondents reported communicating more effectively when ordering in a restaurant.
- Three-quarters (42/55; 76.4%) of the respondents reported communicating more effectively at a dinner party.
- Three-quarters (36/46; 78.3%) of the respondents reported hearing religious services more effectively.
- Over three-quarters (41/48; 85.4%) of the respondents reported communicating more effectively in meetings.

## General performance questionnaire

The General Performance Questionnaire was administered pre- and postoperatively to 51 of 67 clinical trial participants. The 14 item, self-report questionnaire evaluated possible device-related benefits, such as enjoyment of music, ability to monitor individual voice quality, improvements in communication ability and general quality of life issues.

The following statements summarise these self-reported benefits. When using the Nucleus 24:

- Three-quarters (35/51; 69%) of the respondents reported they enjoyed listening to music (at least to some degree) compared to one-third of the respondents (15/51; 29%) preoperatively.
- Two-thirds (32/51; 63%) of the respondents recognised (at least occasionally) songs and tunes that were familiar to them before losing their hearing, compared to 35% (18/51) preoperatively.
- Over one-third (20/51; 39%) of the respondents recognised familiar songs and tunes at least half of the time.
- 86% of the respondents (44/51) reported they could frequently or almost always monitor the loudness and quality of their voice compared to only 35% (18/51) preoperatively.
- 90% (46/51) of the respondents reported an overall improvement in communication ability without lipreading.

## Regarding general quality of life issues

- 88% (45/51) of the respondents indicated that they were satisfied with the cochlear implant system after three months of experience.
- 92% (47/51) of the respondents were happy they made the decision to undergo surgery and receive the implant.
- 92% (47/51) of the respondents indicated that the quality of their lives improved after receiving the Nucleus 24.

# Nucleus 24 and advanced speech processing strategies

The effectiveness of three advanced speech processing strategies, CIS, SPEAK, and ACE™, was assessed in a sample of 51 postlinguistically deafened adults. Prior to the study, all participants had at least three months of experience with the Nucleus 24 cochlear implant, using the SPEAK speech processing strategy. Study participants represented a broad range of postoperative outcomes and were randomly assigned to one of two experimental groups. Following a baseline performance evaluation using SPEAK, 27 subjects assigned to Group A were fitted with an optimised CIS strategy, and 24 subjects assigned to Group B were fitted with an optimised ACE strategy. After six weeks of experience with CIS (Group A) or ACE (Group B), each subject's performance was re-evaluated and compared to his or her SPEAK baseline, using a binomial statistical model. Tests of open set speech recognition included CNC Monosyllabic Words, CUNY Sentences, and HINT Sentences administered in quiet. CUNY Sentences also were presented in background noise at a level that was moderately difficult for the typical cochlear implant recipient (+10 dB signal-to-noise ratio). A comparative questionnaire was administered to each subject at the six week interval, to evaluate strategy preferences in a variety of listening environments.

## Matrix of CIS and ACE™ programming parameters

As shown in the following matrix, the 51 investigational subjects and their audiologists selected different combinations of CIS and ACE programming parameters as optimal. For each participant, the optimal stimulation rate (per channel) is displayed along the x-axis and the optimal number of stimulation sites (channels for CIS and maxima for ACE) is displayed along the y-axis.

As illustrated, study participants selected:

- A wide range of CIS and ACE programming parameters
- Optimal stimulation rates ranging from 720 Hz – 2400 Hz per channel
- Optimal total stimulation rates ranging from 5,760 Hz – 14,400 Hz
- A minimum of six and up to 20 channels (CIS) or maxima (ACE) of stimulation, as optimal.

The broad range of CIS and ACE programming parameters selected by study participants demonstrates the inherent flexibility of the Nucleus 24 system.

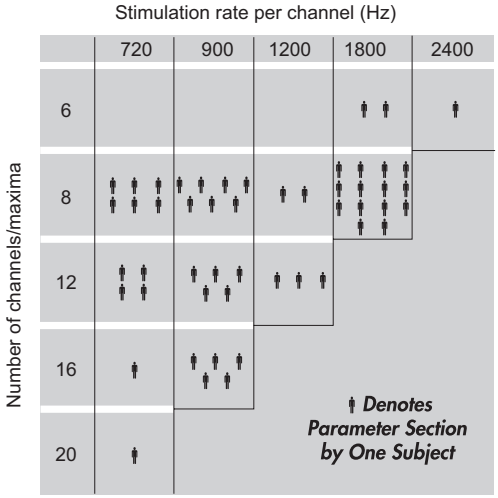


Figure 1: Distribution of CIS and ACE programming parameters for 51 investigational subjects

## Speech perception results for Groups A and B

The 27 adults who converted from the baseline SPEAK strategy to CIS (Group A) recognised an average of:

- 78% of words in open set CUNY Sentences when using SPEAK, compared to 74% when using CIS. Median open set scores for the two strategies were 91% and 92%, respectively.
- 63% of words in open set HINT Sentences when using SPEAK, compared to 61% when using CIS. Median scores were 74% for both SPEAK and CIS.
- 65% of words in CUNY Sentences in the presence of background noise using SPEAK, and 63% with CIS. Median noise scores were 77% and 74%, respectively.
- 39% of monosyllabic words with SPEAK and 35% with CIS. Median open set word recognition scores were 40% (SPEAK) and 42% (CIS).

The 24 adults who converted from the baseline SPEAK strategy to ACE (Group B) recognised an average of:

- 80% of words in CUNY Sentences when using SPEAK, compared to 81% when using ACE. For both strategies, median open set scores were 92%.
- 65% of words in open set HINT Sentences when using SPEAK, compared to 66% with ACE. Median scores were 68% and 66% for SPEAK and ACE, respectively.
- 63% of words in CUNY Sentences in the presence of background noise using SPEAK, and 67% with ACE. Median noise scores were 65% for SPEAK and 74% for ACE.
- 42% of open set CNC Words with SPEAK, and 41% of the words with ACE. Median scores were 37% (SPEAK) and 35% (ACE).

## Speech perception results for individual subjects

- No single speech processing strategy provided optimal performance for all study participants. When evaluated with CUNY Sentences presented in background noise, ten of the 27 subjects (37%) who tried SPEAK and CIS performed best with SPEAK, eight (30%) with CIS, and nine (33%) performed equally well with both strategies. Of the 24 subjects who tried SPEAK and ACE, seven (29%) performed best with SPEAK, nine (38%) with ACE, and eight (33%) performed equally well with both strategies.
- Postlinguistically deafened adult cochlear implant recipients derived significant benefit from access to multiple speech processing strategies and a broad choice of implementation options.

## Questionnaire results

Following six weeks of experience with the new speech processing strategy, a questionnaire was administered to 49 of the 51 study participants. Respondents rated the ease with which they adjusted to the new strategy and also expressed relative preferences for one of the two strategies in a variety of listening environments. For preference-related items, participants were asked to indicate whether they (1) preferred SPEAK, (2) preferred the new strategy (i.e. CIS for Group A and ACE for Group B), (3) perceived SPEAK and the new strategy as equivalent or, (4) were not sure of their preference. The following statements summarise this self-reported information.

Of the 27 adults who converted from SPEAK to CIS:

- One-third (9/27; 33%) of the respondents rated the conversion process as 'easy'.
- Almost half (13/27; 48%) of the respondents preferred SPEAK when listening in quiet, 30% (8/27) preferred CIS, and 19% (5/27) rated the two strategies as equivalent.
- Two-thirds (18/27; 67%) of the respondents preferred SPEAK when listening in background noise, compared to 26% (7/27) who preferred CIS.
- When listening to music, 26% (7/27) and 33% (9/27) of the respondents preferred SPEAK and CIS, respectively.
- When using the telephone, 41% (11/27) of the respondents preferred SPEAK, 7% (2/27) preferred CIS, and 26% (7/27) rated the two strategies as equivalent.
- Over half (14/27; 52%) of the respondents selected SPEAK as their preferred strategy 'overall'.
- One-third (9/27; 33%) of the respondents selected CIS as their preferred strategy 'overall'.

Of the 24 adults who converted from SPEAK to ACE:

- Over half (13/22; 59%) of the respondents rated the conversion process as 'easy'.
- 27% (6/22) of the respondents preferred SPEAK when listening in quiet, 32% (7/22) preferred ACE, and 27% (6/22) rated the two strategies as equivalent.
- 36% (8/22) of the respondents preferred SPEAK when listening in background noise and 32% (7/22) preferred ACE.
- When listening to music, 18% (4/22) of the respondents preferred SPEAK and 18% (4/22) preferred ACE. 23% (5/22) rated the two strategies as equivalent.
- 36% (8/22) of the respondents preferred SPEAK when using the telephone. 18% (4/22) preferred ACE, and 18% (4/22) rated the two strategies as equivalent.
- Almost one-third (7/22; 32%) of the respondents selected SPEAK as their preferred 'overall' strategy.
- 23% (5/22) of the respondents selected ACE as their preferred 'overall' strategy.

After only six weeks of experience using either CIS or ACE:

- Almost three-quarters (35/49; 71%) of the respondents reported an overall preference for one strategy over the other (i.e. Group A: SPEAK or CIS, Group B: SPEAK or ACE).

# Children

Effectiveness of the Nucleus 24 system in older (five years and above) children was assessed by comparing the speech perception abilities of 23 pre- and postlinguistically deafened subjects preoperatively in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) with their postoperative performance in the implanted ear alone, after six months of device use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Recorded versions of various pediatric speech perception measures were presented at 70 dB SPL. Individual subject results were analyzed using a binomial statistical model and group means were analyzed using paired t-tests and the non-parametric Wilcoxon Signed Ranks tests.

Of the children five years of age and older who were capable of being tested on open set word recognition tasks:

- 61% (14/23) demonstrated significant improvement on the Glendonald Auditory Screening Procedure (GASP).
- 44% (10/23) demonstrated significant improvement on the MLNT.
- 57% (13/23) demonstrated significant improvement on the LNT.
- 48% (11/23) demonstrated significant improvement on the Phonetically-Balanced Kindergarten (PBK) monosyllabic word test.

Group mean performance was significantly higher after six months of experience with the Nucleus 24, on all 11 measures of speech perception administered to children five years of age and older. These measures ranged from simple closed-tests to more difficult open set word and sentence recognition tests.

Device effectiveness for older children also was assessed through parental ratings of their child's auditory behaviours in a variety of everyday listening situations on the Meaningful Auditory Integration Scale (MAIS). For 19 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Ratings describing the frequency of occurrence of the child's auditory behaviours ranged from 0 (Never) to 4 (Always). Results were analyzed as the proportion of children rated who demonstrated the specific behaviour either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 83% (15/18) of the children frequently or always responded to their name in quiet compared with only 47% (9/19) preoperatively with hearing aids.
- 47% (9/19) of the children frequently or always responded to their name in noise compared with only 11% (2/19) preoperatively with hearing aids.
- 79% (15/19) of the children frequently or always spontaneously recognised common sounds in the classroom compared with 26% (5/19) preoperatively with hearing aids.

### Younger children (ages 18 months to 4 years, 11 months)

Effectiveness of the Nucleus 24 system in younger children was assessed in part through parental ratings of their child's auditory behaviours in a variety of everyday listening situations on the MAIS. For 22 children, preoperative ratings in the best-aided condition (implanted ear aided, non-implanted ear aided or binaurally aided) were compared with postoperative ratings after six months of implant use. Postoperatively, the Nucleus 24 system was programmed to implement the SPEAK speech processing strategy. Ratings describing the frequency of occurrence of the child's auditory behaviours ranged from 0 (Never) to 4 (Always). Results were analyzed as the proportion of children rated who demonstrated the specific behaviour either 'frequently' or 'always'.

After six months of experience with the Nucleus 24:

- 68% (15/22) of the children frequently or always responded to their name in quiet compared with only 27% (6/22) preoperatively with hearing aids.
- 45% (10/22) of the children frequently or always responded to their name in noise compared with only 14% (3/22) preoperatively with hearing aids.
- 41% (9/22) of the children frequently or always spontaneously recognised common sounds in the classroom compared with 14% (3/22) preoperatively with hearing aids.

## Neural Response Telemetry (NRT™)

The Neural Response Telemetry (NRT™) system of the Cochlear Nucleus CI512 cochlear implant is capable of detecting physiological responses of elements of the auditory nerve within the cochlea.

# Clinical considerations

Adult and pediatric patients deafened from birth to two years of age are considered to be prelinguistically deafened, while those with an onset of deafness from two to five years of age are considered to be perilinguistically deafened. Postlinguistically deafened patients typically are deafened after the age of five and present with age-appropriate speech and language skills.

Optimised hearing aid fitting and evaluation procedures are critical to the selection of suitable cochlear implant candidates. In order to ensure selection of appropriate candidates, hearing healthcare professionals should utilise state of the art amplification and diagnostic instruments, and clinically accepted hearing aid evaluation and fitting procedures.

Adults with severe to profound, postlinguistic, sensorineural hearing loss commonly present with asymmetrical audiometric profiles. When clinically appropriate, it is recommended that the poorer ear be selected for implantation, as surgical placement of the device will result in complete loss of residual hearing in the implanted ear. When selecting the ear for implantation, open set sentence recognition scores with hearing aids should be considered over more conventional audiological measures, as appropriate clinical indicators of preoperative auditory function.

Prelinguistically and perilinguistically deafened adults who do not have functional oral speech and language skills, and who are not highly motivated to participate in the rehabilitation process, are more likely to become non users of the device than are other adult patients. Prospective patients and their families should be counseled extensively regarding the limited nature of expected postoperative benefits, and should understand that prelinguistically and perilinguistically deafened adults are at risk for device non use.

Many prelinguistically and perilinguistically deafened adults demonstrate improved detection of medium to loud environmental sounds, including speech. A few individuals demonstrate improved lipreading abilities, following extensive rehabilitation. (Average test scores improved by less than 10%, when the device was used in conjunction with lipreading.)

There was no significant difference in performance between the SPrint (body worn) and the ESPrit (ear level) processors on any measure of open set speech perception in quiet or in noise.

# Other information

## Patient counselling

### Preoperative counselling

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

## Storage, handling and sterilisation

Transport and store Nucleus implants at temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

For long term storage, store at ambient room temperature. Keep dry.

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

The implant, non-magnetic plugs and replacement magnets are single-use items. The non-magnetic plugs and replacement magnets are supplied separately.

All of the above components are supplied in sterile packaging. Ethylene oxide processing is indicated by a green dot 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 pack containing the implant is ruptured
- exposure to ethylene oxide processing is not indicated.

# Information for use and recommended training

Physicians should be very experienced in mastoid surgery and the facial recess approach to the round window. It is important that physicians be trained in the implantation procedure for the CI500 Series and Nucleus 24. It is strongly recommended that the surgeon work with an experienced team of audiology, speech-language, rehabilitation, education and psychology professionals. It is recommended that audiology professionals attend a training program for this device. Cochlear Americas conducts periodic training courses.

For product-specific information, refer to the Surgeon's Guide supplied with each implant.

# Notes

# Notes

# Notes

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



*Hear now. And always*

491849 ISS5 FEB20

CI522

Cochlear™

# Nucleus® CI522 cochlear implant with Slim Straight electrode

## Physician's Guide

Hear now. And always

Cochlear®

# About this guide

This guide applies to the Cochlear™ Nucleus® CI522 cochlear implant, which is a CI500 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 (15.4 lb) or greater.*
- To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist 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 CI522 implant is MR Conditional. MRI is contraindicated except under specific circumstances. See *MRI safety information* on page 51.

## Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, or electrode lead.
- **Ionizing radiation therapy** can cause damage to the implant. Do not use ionizing 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 CI500 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 the electrical stimulation of the auditory nerve.

### Adults

Cochlear Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

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

# Contraindications

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

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlear development
- tympanic membrane perforation in the presence of active middle ear disease.

# 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.

# Summary of adverse events

The following information summarizes adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant.

## Adults

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

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

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

## Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

### Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

### Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

### Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

## Loss of residual hearing

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

# 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

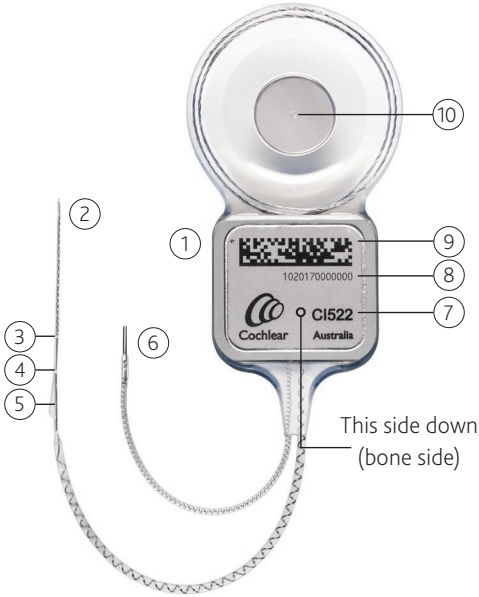
The external components include a sound processor, and associated accessories and cables.

The system is programmed by a Cochlear proprietary programming system.

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

# The Cochlear™ Nucleus® CI522 cochlear implant with Slim Straight electrode

The CI522 implant is a CI500 Series implant.

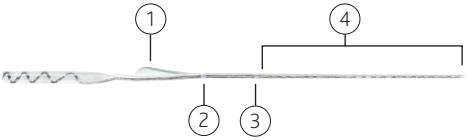



1 Receiver/stimulator (printed information on bone side)
2 Intracochlear electrode
3 White marker indicating 20 mm insertion depth
4 White marker indicating 25 mm (max) insertion depth
5 Handle
6 Extracochlear electrode
7 Model name
8 Serial number
9 Barcode
10 Magnet (blank on bone side)

Figure 1: CI522 cochlear implant with Slim Straight electrode (bone side)


1 Magnet (grey ring on skin side)
2 Extracochlear electrode (plate) to face upwards/skin
3 Intracochlear electrode

Figure 2: CI522 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 3: Slim Straight electrode

# Surgical instruments

Instruments for use during surgery are available in a Surgical Instrument Kit and can also be ordered individually.

## Surgical Instrument Kit

The Surgical Instrument Kit is appropriate for use with CI500 Series implants. A CI500 Series upgrade kit is also available.

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

### BTE Template

Used to ensure the implant is positioned with sufficient space for a behind-the-ear sound processor.

Figure 4: BTE Template

### CI500 Series Recess Gauge

Used to mark the bone recess on the skull, and measure the depth of the bone recess after drilling.


Figure 5: CI500 Series Recess Gauge

## CI500 Series Implant Template

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


Figure 6: CI500 Series Implant Template

## Contour® Electrode Claw

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

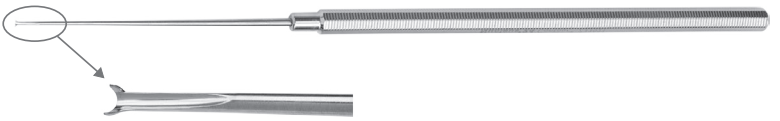


Figure 7: Contour Electrode Claw

## AOS™ (Advance Off-Stylet®) Forceps

Used to grasp or hold the intracochlear electrode during insertion of the electrode into the cochlea. Curved tip ends gently cup the array, improve stability and minimise rotation.

Figure 8: AOS Forceps

# Other instruments

Surgical instruments that can be ordered individually are described below.

## Spacer for Intraoperative Testing

Used to check that there is at least 2 mm between the processor coil and implant coil when the processor coil is placed directly over the implant coil.

The Spacer is non-sterile.

**Caution**

Do not sterilise. A sterile sheath is required for use.


Figure 9: Spacer

## CI500 Series Non-sterile Silicone Implant Template

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

**Warning**

Do not sterilise. Do not use in the sterile field. Single-use item.

Figure 10: CI500 Series Non-sterile Silicone Implant Template

## CI500 Series Sterile Silicone Implant Template

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

One Sterile Silicone Implant Template is packaged with each implant. For more information see warnings below and ***2. Opening the CI500 Series Sterile Silicone Implant Template*** on page 27.

Figure 11: CI500 Series Sterile Silicone Implant Template

### 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 template becomes non-sterile e.g. if it is dropped or mishandled in theatre after removal from packaging.
- Use with CI500 Series implants only.

# Surgical procedure

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

The surgical procedure includes the following:

1. "Pre-incision: non-sterile field" – page 26
2. "Opening the CI500 Series Sterile Silicone Implant Template" – page 27
3. "Incision" – page 28
4. "Mastoidectomy and preparing the bone recess" – page 29
5. "Drilling tie-down holes" – page 32
6. "Opening the facial recess" – page 33
7. "Preparing the cochleostomy or round window" – page 34
8. "Inspecting the cochlear implant and electrodes" – page 37
9. "Positioning and securing the implant" – page 38
10. "Securing the extracochlear electrode" – page 39
11. "Inserting the intracochlear electrode" – page 40
12. "Securing and sealing the intracochlear electrode" – page 42
13. "Performing intraoperative measurements" – page 44
14. "Closure" – page 45

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments*** on page 21.

# 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.
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 CI500 Series Sterile Silicone Implant Template

One CI500 Series Sterile Silicone Implant Template is packaged with each implant. For more information on use of the Template see ***CI500 Series Sterile Silicone Implant Template*** on page 24.

**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 with 'CI500 series' written in it. The tray containing the cochlear implant displays the Cochlear logo.

   **Warning**

   If the sterile pack 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, i.e. 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 anterio-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.

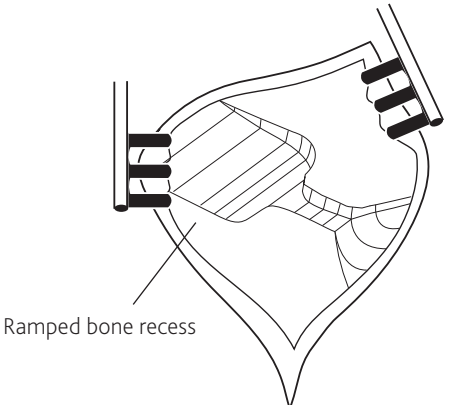
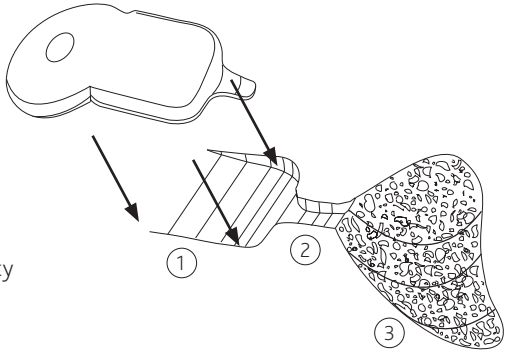



Figure 12: Ramped bone recess

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




1 Ramped bone recess
2 Channel
3 Mastoidectomy cavity

Figure 13: 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 (see Figure 13). 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 (see *The bone recess* on page 29), 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.

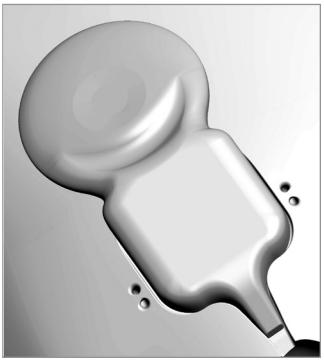


Figure 14: Tie-down holes for CI500 Series implants

**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 CI522 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 see *11. Inserting the intracochlear electrode* on page 40.

## 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.

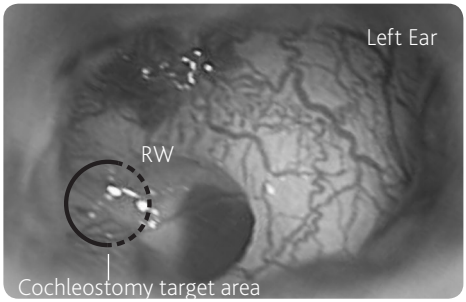



Figure 15: Cochleostomy target area

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 40.

## 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.

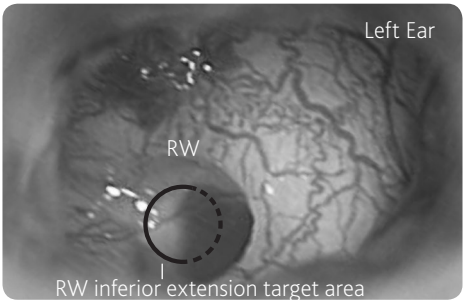



Figure 16: Round window target area

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 40.

# 8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked see *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 27.

**Sterile field**

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

### Warning

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 damage to 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/pericranial pocket between the tie-down holes.

   For information on correct implant orientation see *Device description* on page 18.

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**

   In case the magnet requires removal at a later date, do not suture directly over the magnet.

# 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**

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, stretch or bend the electrode.

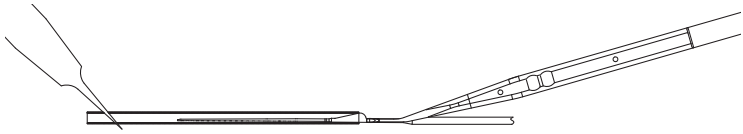


Figure 17: Removing the tube

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.

**Warning**

Do not force if resistance is felt before full insertion.

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.

   **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 see 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 sheath.

   **Warning**

   If using the Intraoperative Spacer, place the coil on top of the Intraoperative Spacer in the sterile sheath.
3. Place the external coil over the implant magnet.

   **Note**

   - The transmitting range of the cochlear implant is 1 mm to 10 mm.
   - 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.

# Notes

# 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 three to four weeks after the operation. 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

Complete the registration form. Send the completed form to Cochlear within 30 days of receiving the product. Fill out the implant model number and ear details on the patient identification card and give it to the patient or their carer.

The patient or their carer should carry the patient identification 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 (see *Cutting the intracochlear electrode lead* on page 49).
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 18: 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 problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

# Notes

# MRI safety information


The Cochlear Nucleus CI522 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.


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

# Removing the magnet

## ⚠ Caution

- Take care when removing or inserting the magnet or non-magnetic plug, so as not to damage the implant silicone. Exerting minimal force, always use a blunt instrument – such as an elevator – to lift the lip of the silicone elastomer recess. Minimise the pressure applied to the antenna of the implant.
- Magnets for the Cochlear Nucleus CI500 Series implants are a different size to magnets for the Cochlear Nucleus CI24RE Series implants. Ensure that the correct magnet is used.
- Non-magnetic plugs for the Cochlear Nucleus CI500 Series implants are a different size to non-magnetic plugs for the Cochlear Nucleus CI24RE Series implants. Ensure that the correct non-magnetic plug is used.

## Removing the magnet before implantation

If a new recipient has a condition that will require future MRI examinations, it may be appropriate to replace the magnet with a non-magnetic plug (available from Cochlear) before the device is implanted.

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter coil in place. Retainer discs are available from Cochlear.

The replacement procedure should take place under sterile conditions.

To replace the magnet before implantation:

1. In sterile conditions, remove the cochlear implant from its sterile packaging and place it on a flat and stable surface, with the magnet's cochlear logo or grey ring (denoting polarity) facing up (see magnet images in ***Replacing the magnet*** on page 57). Do not remove the electrode array protective tube.
2. Using an elevator or similar instrument, lift the lip of the silicone elastomer recess around the magnet and remove the magnet from the implant. When removing the magnet, minimise the pressure applied to the implant coil.
3. Remove the sterile non-magnetic plug from its packaging and insert it into the recess. Lift the lip of the recess using an elevator and press the plug into position, being careful not to exert undue pressure on the implant.

   The implant is now ready for implantation.

Replace the magnet when there is no further need for MRI examinations, following the steps in ***Replacing the magnet*** on page 57.

## Removing the magnet after implantation

Remove the magnet in sterile conditions, using either general or local anaesthetic:

1. Make a small incision ensuring there is good access to the magnet.
2. Cut through any fibrous growth around the implant and expose the magnet.
3. Using an elevator or similar instrument, carefully lift the lip of the silicone elastomer recess and remove the magnet. If a retaining suture runs across the magnet, move the suture out of the way.

   The surgical technique then differs according to whether the patient requires a single MRI examination or multiple examinations over a period of time.

### Single MRI

For a single MRI examination:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 54) and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing.
3. Take the patient for the MRI examination.
4. After the MRI has been taken, under sterile conditions insert a new sterile replacement magnet following the steps in ***Replacing the magnet*** on page 57.

## Multiple MRI

For cochlear implant recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the plug prevents fibrous tissue growing into the recess. Such growth would make magnet replacement difficult.

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter coil in place. Retainer discs are available from Cochlear.

When there is no further need for MRI examinations, the plug is removed and replaced by a magnet.

The non-magnetic plug and replacement magnet are supplied separately in sterile packs. Both are single-use items.

# Inserting a non-magnetic plug

To insert a sterile non-magnetic plug in the recess:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 54) and remove the magnet.
2. Lift the lip of the recess using an elevator and press the non-magnetic plug available from Cochlear into position, being careful not to exert undue pressure on the implant.


Figure 19: CI500 Series non-magnetic plug

**Caution**

Non-magnetic plugs for CI500 Series implants are a different size to non-magnetic plugs for CI24RE Series implants. Ensure the correct plug is used.

3. Close the wound in layers.
4. When MRI is no longer a regular necessity, insert a replacement magnet by following the steps in ***Replacing the magnet*** on page 57.

# Replacing the magnet

When MRI is no longer a regular necessity:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 54) exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a new sterile replacement magnet, available from Cochlear, with the Cochlear logo or grey ring (denoting polarity) facing up, as shown below.

Figure 20: CI500 Series magnets facing upwards

Use the elevator to lift the lip of the recess and position the magnet.

**Caution**

Magnets for CI500 Series implants are a different size to magnets for CI24RE Series implants. Ensure the correct magnet is used.

**Note**

As with the original magnet, the silicone lip retains the replacement magnet.

4. Close the wound in layers.

For additional information about magnet removal, contact Cochlear.

# Notes

# How the implant is supplied

The implant, non-magnetic plugs and replacement magnets are single-use items. Non-magnetic plugs and replacement magnets 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 pack containing the implant is ruptured
- exposure to ethylene oxide processing is not indicated by a green dot on the sterile pack.

## Storage and handling

Transport and store Nucleus cochlear implants at temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

For long term storage, store at room temperature. Keep dry.

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

# CI522 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 | 0.19 $mm^2$ to 0.14 $mm^2$ |
| Active array length when straightened | 19.1 mm |
| Nominal electrode length when straightened | • 20 mm from tip to distal marker<br>• 25 mm from tip to proximal marker |
| Lead length from receiver/ stimulator to array tip | 105 mm |

| Extracochlear electrodes |
|---|
| • Plate on receiver/stimulator<br>• Cylindrical electrode 0.6 mm (typical) diameter with lead length 60 mm |

| Receiver/Stimulator | |
|---|---|
| Dimensions | Case: 24 mm x 23 mm x 3.9 mm<br>Coil: 31 mm diameter x 3.7 mm thick |
| Volume | 3.9 $cm^3$ without lead |
| Weight | 8.6 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 |
| 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 |
| Transmitting range | 1 to 10 mm |

| 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, bipolar and common ground modes |
| Impedance measurement accuracy | 80% measured according to EN 45502-2-3 |
| 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 |
| Titanium | Receiver/stimulator case<br>Magnet 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.

# Symbols

The following symbols may appear on your implant packaging:

| | |
|---|---|
|  | Fragile, handle with care |
|  | Do not use if package is damaged |
|  | Refer to instruction manual |
|  | 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 |
|  | Temperature limits |
|  | Keep dry |
| STERILE EO | Sterilised using ethylene oxide |
| Rx Only | Caution: US law restricts this device to sale by, or on the order of, a physician |
| REF | Catalogue number |
| SN | Serial number |

| | |
|---|---|
| LOT | Batch code |
| EC REP | Authorised representative in the European Community |
| MR | MR Conditional |

# Notes

# Notes

# Notes

# Cochlear™

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



*Hear now. And always*

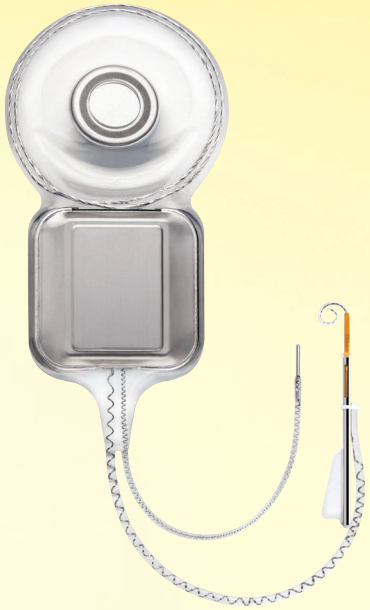
538751 ISS4 FEB20

CI532

# Cochlear™

## Nucleus® CI532 cochlear implant with Slim Modiolar electrode

Physician's Guide



Hear now. And always

Cochlear®

# About this guide

This guide applies to the Cochlear™ Nucleus® CI532 cochlear implant, which is a CI500 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. This 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 this entire 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.
- To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist should be present during surgery for infants implanted under 12 months of age.

### 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 CI532 implant is MR Conditional. MRI is contraindicated except under specific circumstances. See *MRI safety information* on page 64.

## Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, or electrode lead.
- **Ionizing radiation therapy** can cause damage to the implant. Do not use ionizing radiation therapy directly over the implant.

## Notes

- **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.
- For device electromagnetic compatibility (EMC) information, see *Electromagnetic Compatibility (EMC)* on page 75.

# Intended use and indications

## Intended use

Cochlear Nucleus CI500 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 of the auditory nerve.

### Adults

Cochlear Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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 tape-recorded tests of open set sentence recognition.

## Children

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

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

# Contraindications

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

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlear development
- tympanic membrane perforation in the presence of active middle ear disease.

# 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.

# Summary of adverse events

The following information summarizes adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant.

## 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 twenty-seven US sites. Twenty patients experienced either a medical/surgical or device-related complication.

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

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

## Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

### Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

### Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

### Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

## Loss of residual hearing

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

# 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.

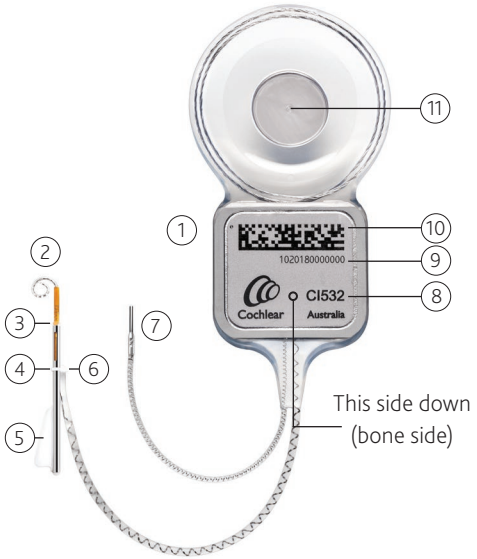
The system is programmed by a Cochlear proprietary programming system.

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

# The CI532 cochlear implant with Slim Modiolar electrode

The CI532 cochlear implant has a receiver/stimulator, which receives and decodes the electrical signal from the sound processor, and an electrode array, which delivers the signal to the cochlea.

The CI532 implant is a CI500 Series implant.




1 Receiver/stimulator (printed information on bone side)
2 Intracochlear electrode
3 Sheath stopper
4 White alignment marker on sheath
5 Sheath handle
6 White alignment marker on intracochlear electrode
7 Extracochlear electrode
8 Model name
9 Serial number
10 Barcode
11 Magnet (blank on bone side)

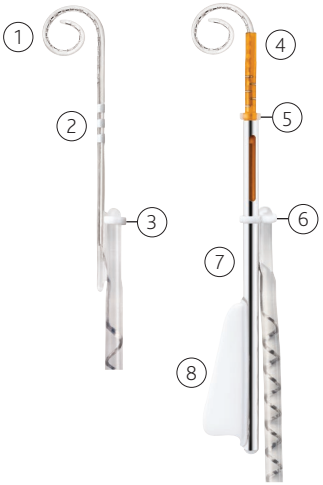
Figure 1: CI532 cochlear implant with Slim Modiolar electrode (bone side)


1 Magnet (grey ring on skin side)

2 Extracochlear electrode (plate) to face upwards/skin

3 Intracochlear electrode with sheath

Figure 2: CI532 cochlear implant with Slim Modiolar electrode (skin side)




1 Intracochlear electrode

2 Three white insertion depth markers, visible only after sheath is removed

3 White alignment marker on intracochlear electrode

4 Sheath tip

5 Sheath stopper

6 White alignment marker on sheath (when electrode is fully inserted, aligns with white alignment marker on electrode)

7 Sheath guide tube

8 Sheath handle

Figure 3: Slim Modiolar electrode with sheath removed and with sheath

# Surgical instruments

## Instruments supplied in implant kit

A Sterile Silicone Implant Template and Cochleostomy Sizing Tool are provided in the surgical kit.

The Sterile Silicone Implant Template is packed in the tray with the blue seal. The Cochleostomy Sizing Tool is packed in the implant tray with the white seal.

These instruments are sterile. They are designed for single use and are not resterilisable.

### 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 instruments become non-sterile e.g. if dropped or mishandled in theatre after removal from packaging.
- After surgery it is advisable to dispose of the instruments, even if not used.
- Dispose of instruments according to your institution's policy for disposal of biohazardous waste.
- Use with CI532 cochlear implants only.

## CI500 Series Sterile Silicone Implant Template

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

One Sterile Silicone Implant Template is packaged with each implant. For more information see warnings above and ***6. Opening the Sterile Silicone Implant Template*** on page 28.

Figure 4: CI500 Series Sterile Silicone Implant Template

## Cochleostomy Sizing Tool

Packed in the implant tray (white seal).

Used to determine/check the size of the cochleostomy or round window, to confirm if the electrode with sheath will fit.

Using the sizing tool to test the opening confirms if the sheath stopper will prevent the sheath and electrode from advancing too far into the cochlea.

1 Stopper – 1.4 mm diameter
2 Tip – 0.8 mm diameter


Figure 5: Cochleostomy Sizing Tool

# Surgical Instrument Kit for CI500 Series

The Surgical Instrument Kit is appropriate for use with CI500 Series implants. A CI500 Series upgrade kit is also available.

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

## BTE Template

Used to ensure the implant is positioned with sufficient space for a behind-the-ear sound processor.

Figure 6: BTE Template

## CI500 Series Recess Gauge

Used to mark the bone recess on the skull, and measure the depth of the bone recess after drilling.


Figure 7: CI500 Series Recess Gauge

## CI500 Series Implant Template

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


Figure 8: CI500 Series Implant Template

## Contour® Electrode Claw

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

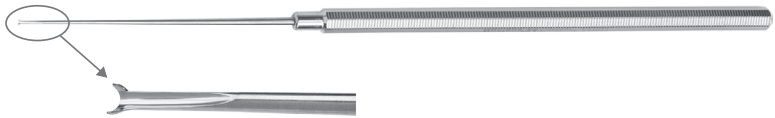


Figure 9: Contour Electrode Claw

## AOS™ (Advance Off-Stylet®) Forceps

Used to grasp or hold the intracochlear electrode during insertion of the electrode into the cochlea. Curved tip ends gently cup the array, improve stability and minimise rotation.

Figure 10: AOS Forceps

# Other instruments

Surgical instruments that can be ordered individually are described below.

## Spacer for Intraoperative Testing

Used to check that there is at least 2 mm between the processor coil and implant coil when the processor coil is placed directly over the implant coil.

The Spacer is non-sterile.

**Caution**

Do not sterilise. A sterile sheath is required for use.


Figure 11: Spacer

## CI500 Series Non-sterile Silicone Implant Template

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

**Warning**

Do not sterilise. Do not use in the sterile field. Single-use item.

Figure 12: CI500 Series Non-sterile Silicone Implant Template

## Slim modiolar electrode sheath

Replacement sheath, used if the primary sheath is damaged or removed from the sterile field

1 Sheath handle
2 White alignment marker
3 Stopper – 1.4 mm diameter
4 Sheath tip


Figure 13: Slim Modiolar Electrode Sheath

# Surgical procedure

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

The surgical procedure includes the following:

1. "Pre-incision: non-sterile field" – page 27
2. "Opening the Sterile Silicone Implant Template" – page 28
3. "Incision and periosteal pocket" – page 29
4. "Mastoidectomy and preparing the bone recess" – page 30
5. "Drilling tie-down holes" – page 33
6. "Opening the facial recess (Posterior Tympanotomy)" – page 34
7. "Preparing the round window or cochleostomy" – page 35
8. "Inspecting the implant, electrodes and sizing tool" – page 39
9. "Positioning and securing the implant" – page 40
10. "Securing the extracochlear electrode" – page 41
11. "Inserting the intracochlear electrode" – page 42
12. "Securing and sealing the intracochlear electrode" – page 54
13. "Performing intraoperative measurements" – page 56
14. "Closure" – page 57

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments*** on page 20.

# 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.
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.

# 6. Opening the Sterile Silicone Implant Template

One Sterile Silicone Implant Template is packaged with each implant. For warnings and more information see *Instruments supplied in implant kit* on page 20.

To open the template tray:

**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 template has a blue stripe. The tray containing the cochlear implant and sizing tool displays the Cochlear logo and has a white seal.

   **Warning**

   If the sterile pack is damaged do not use the template.

**Sterile field**

4. Remove the template tray (blue stripe) and break the seal.
5. Lift the Sterile Silicone Implant Template from the tray.

   **Note**

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

# 6. Incision and periosteal pocket

**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, i.e. under the temporalis muscle.

# 6. 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.

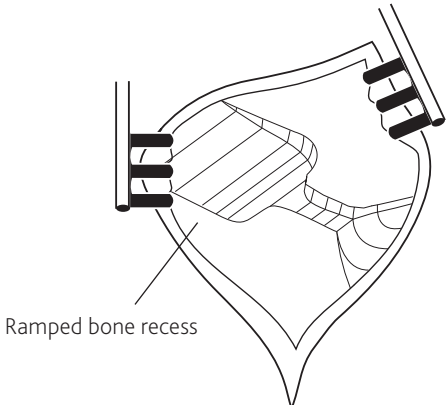
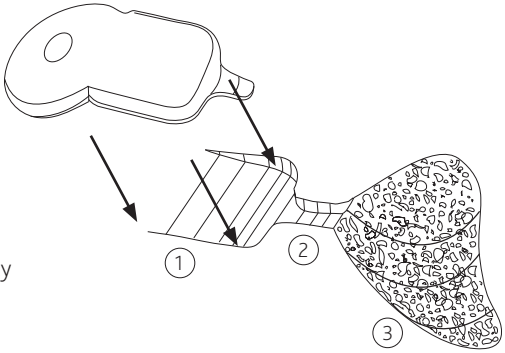



Figure 14: Ramped bone recess

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 15: 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 (see Figure 15). The channel will help protect the electrode against trauma.
6. Use the Recess Gauge to check the position and depth of the electrode exit.

# 7. Drilling tie-down holes

1. Using the implant seat for orientation (see *The bone recess* on page 30), 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 16: Tie-down holes for CI500 Series implants

**Warning**

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

# 3. Opening the facial recess (Posterior Tympanotomy)

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.

# 3. Preparing the round window or cochleostomy

The CI532 implant electrode is compatible with both the round window and cochleostomy approaches.

This section describes site preparation for both approaches. For details on inserting the electrode array see *11. Inserting the intracochlear electrode* on page 42.

**Caution**

The recommended cochlea opening is between 0.8 mm and 1.0 mm wide.

The Cochleostomy Sizing Tool can be used to check the size during drilling and the final size of the opening.

If the opening is larger than 1.4 mm, use the forceps holding the sheath handle to stabilise the sheath and ensure the stopper stays at the round window or cochleostomy opening.

**Warning**

Do not suction the perilymph.

## 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.

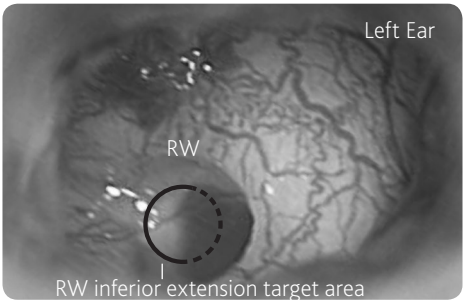



Figure 17: Round window target area

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 42.

## 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 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.

3. Drill sufficient bone to expose at least 0.8–1.0 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 42.

4. Remove the final layer of bone.

# 5. Inspecting the implant, electrodes and sizing tool

If the Sterile Silicone Implant Template is not unpacked see *2. Opening the Sterile Silicone Implant Template* on page 28.

1. Remove the implant tray (white seal) from the packaging.
2. Tear open the seal of the implant tray and check the tray contains an implant and a Cochleostomy Sizing Tool.
3. Remove the implant.
4. Confirm the implant is not damaged and the electrode is contained within the sheath.

**Warning**

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 damage to the cochlear implant:

- minimise handling of the electrode
- do not bend the electrode as it is malleable and will deform.
- leave the sheath on the electrode until just after insertion.

# 5. Positioning and securing the implant

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

   For information on correct implant orientation see *Device description* on page 17.

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**

   In case the magnet requires removal at a later date, do not suture directly over the magnet.

# 4. 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.

# 5. Inserting the intracochlear electrode

## Before insertion

The following should be performed immediately before inserting the electrode.

### Round window

Make a straight incision the width of the round window.

### 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**

Do not suction the perilymph.

## Overview of insertion steps

Figure 18: Steps for inserting electrode into the cochlea

### Note

To prevent movement of the electrode in the cochlea:

- Before the insertion, ensure the lead is not twisted or coiled.
- Hold the sheath handle in forceps to introduce the electrode into the cochlea.
- Maintain hold and control of the electrode until it is fully inserted, the sheath is removed and the lead is stabilised.

### Caution

If resistance is felt during insertion, stop immediately, withdraw the sheath and assess the exposure of the round window/ cochleostomy opening. You should be able to advance the electrode without resistance. Do not use force.

### Warning

If the cochleostomy/round window incision is wider than 1.4 mm or significant resistance is felt during array insertion, use both hands to stabilise before continuing. This will help prevent the sheath stopper advancing through the opening.

## Insertion

To insert the intracochlear electrode into the cochlea:

A. Hold the sizing tool by the handle with AOS Forceps. Insert the sizing tool into the cochleostomy/round window opening until the silicone stopper reaches the cochlea opening. Ensure that the tip of the sizing tool easily enters the cochlea opening and the stopper doesn't advance through the opening.

   This is to check the cochlea opening width is between 0.8 mm and 1.0 mm.

B. Put the sizing tool down. Use blunt-nosed forceps with serrated tips to take hold of the electrode by the sheath handle.

C. Holding the sheath handle securely, use AOS Forceps to gently hold the electrode lead below the white alignment marker as shown. To straighten the intracochlear electrode, slowly retract the electrode until it is fully inside the sheath and resistance is encountered.

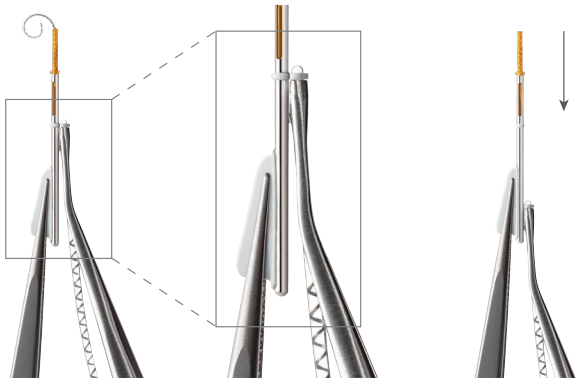


Figure 19: Straightening the intracochlear electrode

D. Hold the sheath handle with forceps and direct the sheath and electrode array towards the opening of the cochleostomy/ round window. Orientate the sheath handle toward the modiolus so the electrode curve follows the cochlea spiral, ensuring it is guided through the scala tympani with stimulating pads facing the modiolus. Guide the sheath into the cochlea until the sheath stopper reaches the cochleostomy/round window.

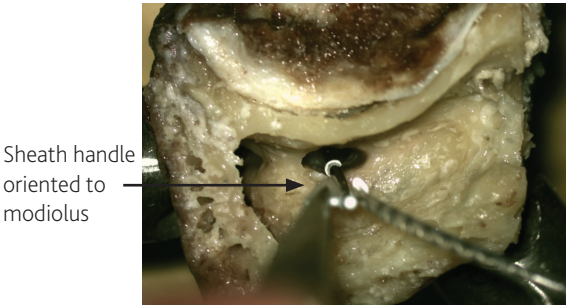



Figure 20: Inserting sheath tip into cochleostomy/round window opening (right ear temporal bone shown)

## Caution

If resistance is felt during insertion, stop immediately, withdraw the sheath and assess the exposure of the round window/cochleostomy opening. You should be able to insert the sheath to the stopper without resistance. Do not use force.

## Notes

- Ensure correct orientation of the electrode in the scala tympani.

  Use the white sheath handle as a guide for correct orientation. The handle should be orientated towards the modiolus and follow the plane of the scala tympani.

  If the handle is not aligned correctly, the electrode tip could move down towards the floor of the scala tympani or up towards the basilar membrane, meaning electrode placement will be sub-optimal with compromised positioning in the scala tympani.

  Be aware of the lead coiling from the electrode to receiver/ stimulator as this could also impact electrode direction.

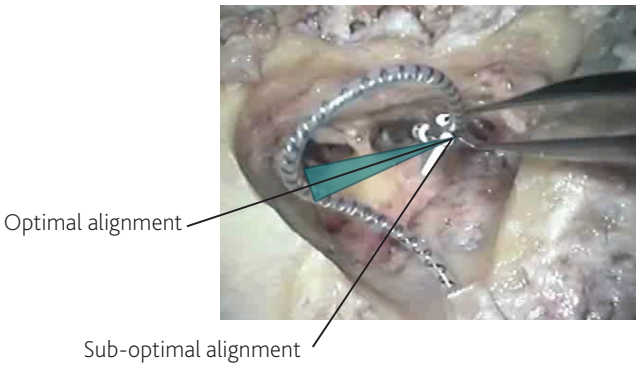



Figure 21: Aligning handle along medial plane of scala tympani

- Ensure the electrode remains in the sheath during insertion.

  During insertion, do not hold the electrode to insert the sheath up to the stopper.

  Hold only the sheath handle until the stopper is at the cochleostomy/round window entrance. Then use your other hand to advance the electrode through the sheath.

  This can prevent the electrode tip from prematurely advancing from the sheath before the stopper is correctly positioned against the cochlea opening.

Figure 22: Electrode tip visible from end of sheath before reaching cochleostomy entrance

## Warning

- Ensure the sheath stopper remains against the cochleostomy/round window opening.

  Ensure the sheath stopper is at the cochleostomy/round window. If the electrode is advanced before the stopper reaches the cochleostomy/round window, the tip could fold over.

  If the cochleostomy/round window opening is too large, use AOS Forceps to hold the electrode and, with your other hand, use forceps to stabilise the sheath stopper at the entrance to prevent the stopper being pushed too far.

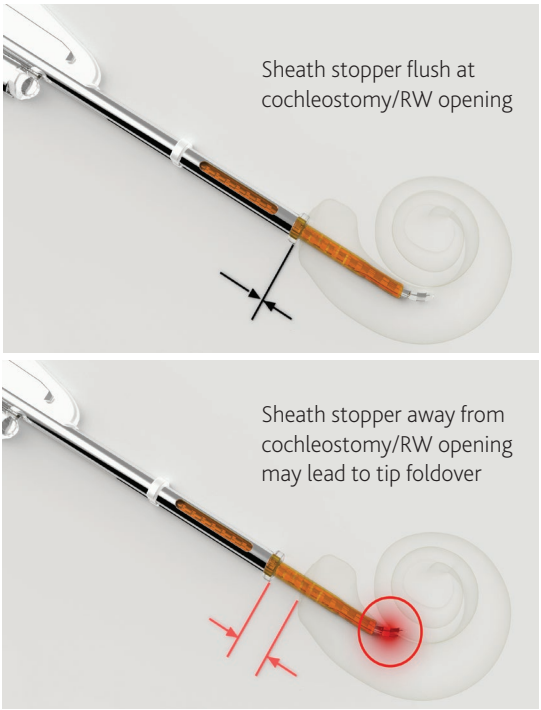



Figure 23: Sheath not flush at opening may result in poor insertion

E. Continuing to hold the sheath handle, use AOS Forceps to grip the electrode lead behind the white marker. Use AOS Forceps to advance the electrode through the sheath guide tube until the white markers are aligned.

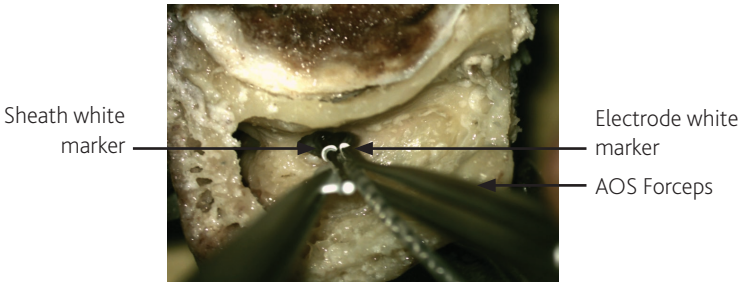



Figure 24: Advancing electrode into cochlea (right ear temporal bone shown)

The electrode array is now fully inserted into the cochlea but the sheath is still attached to the electrode lead.

### Caution

If resistance is felt before full insertion, stop immediately and assess the trajectory and/or position of the sheath. You should be able to advance the electrode without resistance. Do not use force.

F. While continuing to hold the electrode lead with AOS Forceps, use forceps to slowly retract the sheath, sliding it straight back in line with the electrode array until completely disengaged.

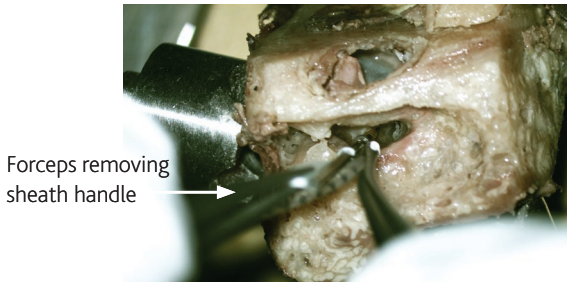



Figure 25: Removing sheath with forceps

G. The electrode is fully inserted in the cochlea with the sheath removed. The three white insertion depth markers can be used to confirm the inserted depth of the electrode. If the three markers are at the cochleostomy/round window opening, a full insertion has been performed.

Ensure the array is not pushed/advanced further into the cochlea to avoid over-insertion and compromised perimodiolar positioning.

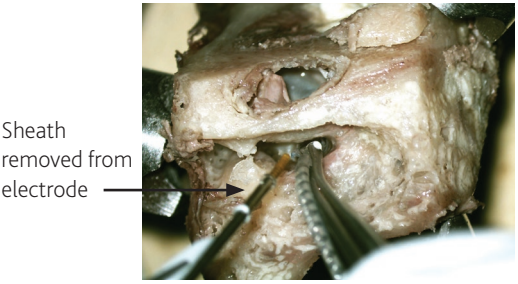



Figure 26: Electrode array fully inserted into cochlea and sheath removed

**Warning**

Ensure the sheath is fully removed. The sheath needs to be completely removed from the electrode and **not** left in place after the procedure is complete.

**Warning**

Keep the sheath in the sterile field in case it is needed for a second insertion attempt. See *Reloading the sheath* on page 51.

## Reloading the sheath

If electrode placement is suboptimal or the sheath is removed prematurely, the electrode may be reloaded for a second insertion attempt.

**Caution**

If the sheath is damaged, use a replacement Slim Modiolar Electrode Sheath.

**Warning**

Do not reload if the electrode is damaged – use a backup implant.

### Opening the replacement sheath

To open the Slim Modiolar Electrode Sheath tray:

#### 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 inner tray is not damaged.

   **Warning**

   If the sterile pack is damaged do not use the sheath.

#### Sterile field

3. Remove the inner tray, break the seal and remove the tray insert.
4. Lift the sheath from the tray.

   **Caution**

   To avoid damaging the sheath, do not hold it by the orange tip – hold the metal section or handle.

## Reloading the electrode into the sheath

1. Hold the sheath handle with forceps. Gently hold the electrode lead with AOS Forceps below the white alignment mark, as shown below.
2. Gently guide the electrode into the sheath tip, as shown below.
3. Slowly retract the electrode until it is completely inside the sheath and cannot be retracted further.

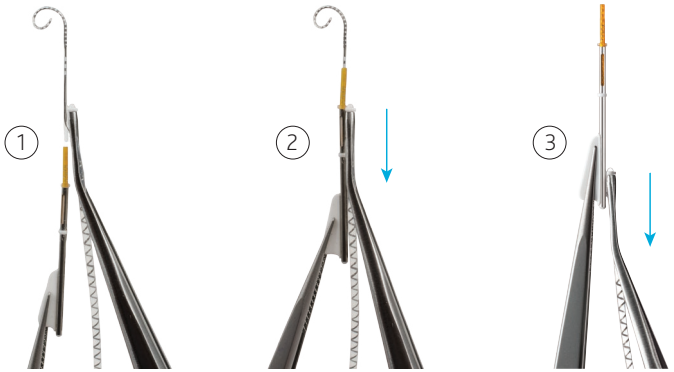



Figure 27: Guiding the electrode into the sheath and retracting the electrode array

### Caution

Check that the electrode is fully contained within the sheath. If not, push the electrode entirely out and repeat from step 1.

4. To check that the electrode and sheath are functioning properly, push the electrode out until the white markers on the electrode array and sheath are aligned.
5. Slowly retract the electrode until it is completely inside the sheath and cannot be retracted further, ready for insertion into the cochlea.

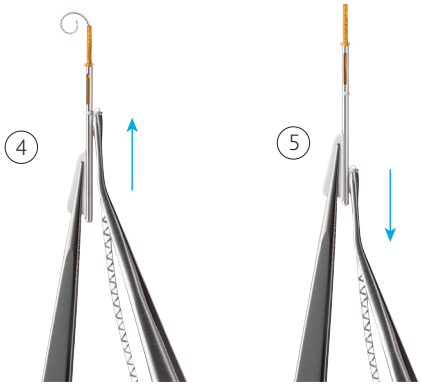



Figure 28: Sliding electrode through sheath and retracting

**Caution**

If the electrode is not fully inside the sheath or they do not function as illustrated above, use a backup implant.

# 6. 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 in place continuously.

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.

   **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 see Xu J, Xu SA, Cohen LT, Clark GM. Cochlear View: Post-operative Radiography for Cochlear Implantation. Am J Otol, 21(1):49-56, 2000.

# 4. 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 sheath.

   **Warning**

   If using the Intraoperative Spacer, place the coil on top of the Intraoperative Spacer in the sterile sheath.
3. Place the external coil over the implant magnet.

   **Note**

   - The transmitting range of the cochlear implant is 1 mm to 10 mm.
   - 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.

# 4. 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 three to four weeks after the operation. 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

Complete the registration form. Send the completed form to Cochlear within 30 days of receiving the product. Fill out the implant model number and ear details on the patient identification card and give it to the patient or their carer.

The patient or their carer should carry the patient identification card with them at all times.

# Identifying the implant

If required, the implant type and model can be identified without the need of surgical intervention, using X-ray or Cochlear programming software.

## Cochlear Nucleus CI24RE Series cochlear implant

This information is to assist with identifying differences between Cochlear Nucleus CI24RE Series and CI500 Series implants. Other implant models may have other identifying features.

Using an X-ray, Cochlear Nucleus CI24RE Series cochlear implants can be identified by the radiopaque characters printed on them.

The characters at the base ('C13T' in Figure 29 below) indicate the following.

- Manufacturer – 'C' indicates 'Cochlear Ltd'.
- Model
  - '4' indicates CI24RE (ST)
  - '5' indicates CI24RE (CA)
  - '13' indicates CI422, as illustrated below.
- Year of manufacture – 'T ' indicates 2004 or later.

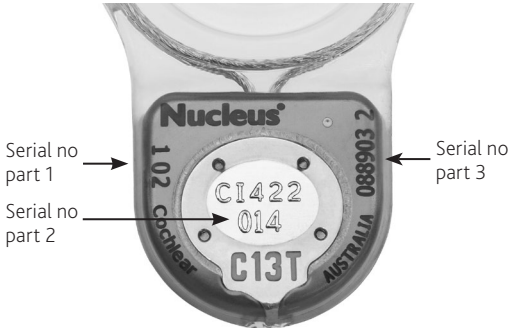



Figure 29: CI422 radiopaque label and serial number

The serial number is in three parts, as labelled in Figure 29, and is read from left to right.

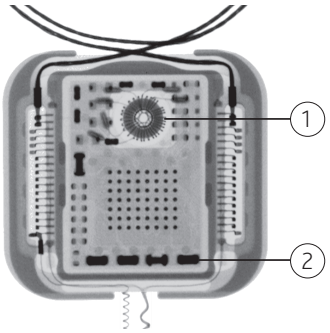
| Serial number part 1 | Serial number part 2 | Serial number part 3 |
|---|---|---|
| 102 | 014 | 0889032 |

## Cochlear Nucleus CI500 Series implant

When interpreting a sagittal X-ray image of a Cochlear Nucleus CI500 Series implant, the device series can be identified by the electronic assembly layout.

Cochlear CI500 Series implants have:

- a round shape at the coil exit end
- four large components at the electrode exit end.




1 Round shape at coil exit end

2 Four large components at electrode exit end

Figure 30: Plain X-ray of CI500 Series implant

# 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 (see *Cutting the intracochlear electrode lead* on page 62).
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.

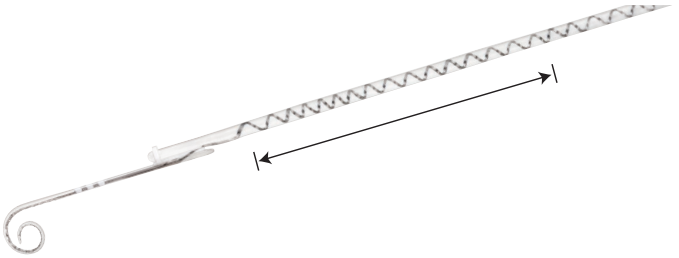


Figure 31: Where to cut electrode lead if required during explantation

# Reporting problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

# Notes

# MRI safety information


The Cochlear Nucleus CI532 implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

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


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

# Removing the magnet

**Caution**

- Take care when removing or inserting the magnet or non-magnetic plug, so as not to damage the implant silicone. Exerting minimal force, always use a blunt instrument – such as an elevator – to lift the lip of the silicone elastomer recess. Minimise the pressure applied to the antenna of the implant.
- Magnets for the Cochlear Nucleus CI500 Series implants are a different size to magnets for the Cochlear Nucleus CI24RE Series cochlear implants. Ensure that the correct magnet is used.
- Non-magnetic plugs for the Cochlear Nucleus CI500 Series implants are a different size to non-magnetic plugs for the Cochlear Nucleus CI24RE Series cochlear implants. Ensure that the correct non-magnetic plug is used.

## Removing the magnet before implantation

If a new recipient has a condition that will require future MRI examinations, it may be appropriate to replace the magnet with a non-magnetic plug (available from Cochlear) before the device is implanted.

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter coil in place. Retainer discs are available from Cochlear.

The replacement procedure should take place under sterile conditions.

To replace the magnet before implantation:

1. In sterile conditions, remove the cochlear implant from its sterile packaging and place it on a flat and stable surface, with the magnet's Cochlear logo or grey ring (denoting polarity) facing up (see magnet images in ***Replacing the magnet*** on page 70). Do not remove the electrode array protective tube.
2. Using an elevator or similar instrument, lift the lip of the silicone elastomer recess around the magnet and remove the magnet from the implant. When removing the magnet, minimise the pressure applied to the implant coil.
3. Remove the sterile non-magnetic plug from its packaging and insert it into the recess. Lift the lip of the recess using an elevator and press the plug into position, being careful not to exert undue pressure on the implant.

   The implant is now ready for implantation.

Replace the magnet when there is no further need for MRI examinations, following the steps in ***Replacing the magnet*** on page 70.

## Removing the magnet after implantation

Remove the magnet in sterile conditions, using either general or local anaesthetic:

1. Make a small incision ensuring there is good access to the magnet.
2. Cut through any fibrous growth around the implant and expose the magnet.
3. Using an elevator or similar instrument, carefully lift the lip of the silicone elastomer recess and remove the magnet. If a retaining suture runs across the magnet, move the suture out of the way.

   The surgical technique then differs according to whether the patient requires a single MRI examination or multiple examinations over a period of time.

### Single MRI

For a single MRI examination:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 67) and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing.
3. Take the patient for the MRI examination.
4. After the MRI has been taken, under sterile conditions insert a new sterile replacement magnet following the steps in ***Replacing the magnet*** on page 70.

## Multiple MRI

For cochlear implant recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the plug prevents fibrous tissue growing into the recess. Such growth would make magnet replacement difficult.

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter coil in place. Retainer discs are available from Cochlear.

When there is no further need for MRI examinations, the plug is removed and replaced by a magnet.

The non-magnetic plug and replacement magnet are supplied separately in sterile packs. Both are single-use items.

# Inserting a non-magnetic plug

To insert a sterile non-magnetic plug in the recess:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 67) and remove the magnet.
2. Lift the lip of the recess using an elevator and press the non-magnetic plug available from Cochlear into position, being careful not to exert undue pressure on the implant.


Figure 32: CI500 Series non-magnetic plug

**Caution**

Non-magnetic plugs for CI500 Series implants are a different size to non-magnetic plugs for CI24RE Series cochlear implants. Ensure the correct plug is used.

3. Close the wound in layers.
4. When MRI is no longer a regular necessity, insert a replacement magnet by following the steps in ***Replacing the magnet*** on page 70.

# Replacing the magnet

When MRI is no longer a regular necessity:

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 67) exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a new sterile replacement magnet, available from Cochlear, with the Cochlear logo or grey ring (denoting polarity) facing up, as shown below.

Figure 33: CI500 Series magnets facing upwards

Use the elevator to lift the lip of the recess and position the magnet.

**Caution**

Magnets for CI500 Series implants are a different size to magnets for CI24RE Series cochlear implants. Ensure the correct magnet is used.

**Note**

As with the original magnet, the silicone lip retains the replacement magnet.

4. Close the wound in layers.

For additional information about magnet removal, contact Cochlear.

# How the implant is supplied

The implant, non-magnetic plugs and replacement magnets are single-use items. Non-magnetic plugs and replacement magnets 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 pack containing the implant is ruptured
- exposure to ethylene oxide processing is not indicated by a green dot on the sterile pack.

## Storage and handling

Transport and store Nucleus cochlear implants at temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

For long term storage, store at room temperature. Keep dry.

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

# CI532 implant specifications

| Intracochlear electrodes | |
|---|---|
| Number of electrodes | 22 electrodes |
| Distance between centres of electrode contacts | 0.6 mm nominal (when curled) |
| Cross-sectional dimensions of array | 0.475 mm x 0.5 mm at proximal end, tapering to 0.35 mm x 0.4 mm at distal end |
| Contact surface area | 0.16 $mm^2$ to 0.19 $mm^2$ |
| Active array length when straightened | 14 mm (distance between most basal and apical electrodes) |
| Lead length | 98 mm from receiver/stimulator to array tip when straightened |
| Markers for insertion depth | Three white, moulded silicone markers. |

| Extracochlear electrodes |
|---|
| • Plate on receiver/stimulator<br>• 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<br>Coil: 31 mm diameter x 3.7 mm thick |
| Volume | 3.9 $cm^3$ without lead |
| Weight without sheath | 8.6 g including electrode arrays |

| 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 |
| Output signal on a 1 kΩ resistor | Amplitude 1750 µA, pulse width 400 µs |
| 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 |
| Transmitting range | 1 to 10 mm |

| 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, bipolar and common ground modes |
| Impedance measurement accuracy | 12.7% measured according to EN 45502-2-3 |
| 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 |
| Titanium | Receiver/stimulator case<br>Magnet case |
| Platinum | Electrode contacts |

# Electromagnetic Compatibility (EMC)

## Guidance and manufacturer's declaration

Cochlear Nucleus Sound Processors, Remote Assistants and Remote Controls are intended for use in the electromagnetic environments specified in this document.

They have been tested and found to be in compliance as shown.

## Electromagnetic emissions

| Emission test | Compliance | Guidance |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 1 | RF energy is only used for its internal function. The RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | | |

Table 1: Electromagnetic emissions

# Electromagnetic immunity

| Immunity test | IEC 60601 test level | Compliance level | Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV and ±15 kV air | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV and ±15 kV air | See ***Electrostatic discharge (ESD)*** in the ***Patient Information*** guide |
| Electrical fast transient/burst IEC 61000-4-4 | Not applicable | | |
| Surge IEC 61000-4-5 | | | |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | | | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 1200 A/m | Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted RF IEC 61000-4-6<br>Radiated RF IEC 61000-4-3 | Not applicable<br>10 V/m 80 MHz to 2.7 GHz | Not applicable<br>20 V/m 80 MHz to 3.0 GHz | See ***Warnings and Cautions for device use*** on page 6, and ***Guidance*** below. |

Table 2: Electromagnetic immunity

## Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance (d):

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

$d = 2.3\sqrt{P}$ 800 MHz to 3.0 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

**Note**

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

Explanatory notes:

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the processor is used exceeds the applicable RF compliance level above, the processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the processor.

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

## Recommended separation distances

Your processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled.

To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 3.0 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

Table 3: Recommended separation distances

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

### Note

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

# 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.

# Symbols

The following symbols may appear on your implant packaging:

| | |
|---|---|
|  | Fragile, handle with care |
|  | Do not use if package is damaged |
|  | Refer to instruction manual |
|  | 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 |
|  | Temperature limits |
|  | Keep dry |
| STERILE EO | Sterilised using ethylene oxide |
| Rx Only | Caution: US law restricts this device to sale by, or on the order of, a physician |
| REF | Catalogue number |
| SN | Serial number |


Batch code


Authorised representative in the European Community


MR Conditional

# Notes

# Notes

# Cochlear™

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Cochlear implant systems are protected by one or more international patents.
The statements made in this guide are believed to be true and correct as of the date of publication. However, specifications are subject to change without notice.



*Hear now. And always*

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CI612

# Cochlear™ Nucleus® CI612 cochlear implant with Contour Advance® electrode

## Physician's Guide

United States of America

Hear now. And always

Cochlear®

# About this guide

**This guide applies to the Cochlear™ Nucleus® CI612 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 (e.g. deep brain stimulators) and magnetic ventricular shunts, as the magnets may affect the function of these devices. The maximum magnetic field strength at one inch (1.0") from the edge of the implant coil (in the plane covering the surface of the head), is less than 300 Gauss.
- To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist 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 CI612 implant is **MR Conditional**. MRI is contraindicated except under specific circumstances. See *MRI safety information* on page 55.

## Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, electrode lead, or exposed magnet cassette cover.
- **Ionizing radiation therapy** can cause damage to the implant. Do not use ionizing 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 of the auditory nerve.

### Adults

Cochlear Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

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

# Contraindications

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

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlear development
- tympanic membrane perforation in the presence of active middle ear disease.

# 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

# Summary of adverse events

The following information summarizes adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant.

## 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/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

## Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

### Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

### Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

### Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

## Loss of residual hearing

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

# 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 system.

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

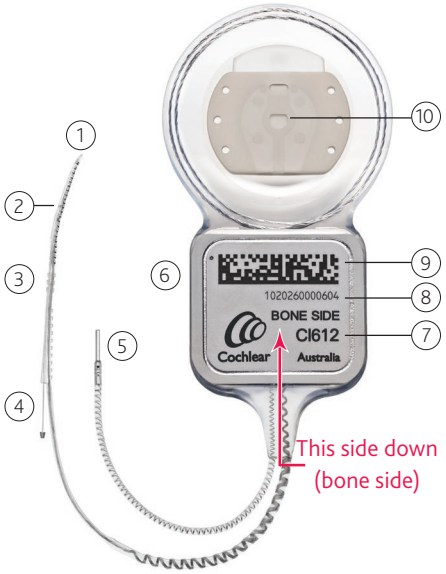
# New features

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: CI612 cochlear implant with magnet cassette partially removed from pocket

# The Cochlear™ Nucleus® CI612 cochlear implant with Contour Advance® electrode

The CI612 implant is a CI600 Series implant.

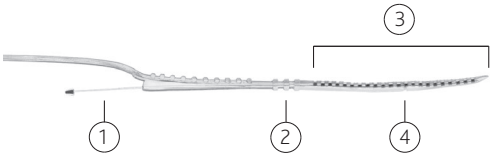



1 Intracochlear electrode (shaped to follow curve of cochlea when stylet is removed)
2 White marker to facilitate AOS insertion
3 Ribs indicating electrode insertion depth
4 Stylet
5 Extracochlear electrode
6 Receiver/stimulator (printed information on bone side)
7 Model name
8 Serial number
9 Barcode
10 Implant coil plate with magnet cassette in pocket

Figure 2: CI612 cochlear implant with Contour Advance electrode (bone side)


1 Implant coil plate with magnet cassette in pocket
2 Extracochlear electrode plate to face upwards (skin side)
3 Contour Advance perimodiolar electrode with stylet in place

Figure 3: CI612 cochlear implant with Contour Advance electrode (skin side)

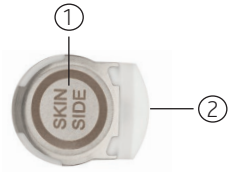



1 Stylet
2 Ribs indicating insertion depth
3 Intracochlear electrode with 22 half-band contacts
4 White marker to facilitate AOS insertion

Figure 4: Contour Advance electrode with stylet


1 Ribs indicating insertion depth
2 White marker to facilitate AOS insertion

Figure 5: Contour Advance electrode with stylet removed




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

Figure 6: Cochlear Nucleus 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 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 Instrument Kit | CI500 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 | ✓ | – |
| Straight Electrode Claw | Z30090 | – | – |
| Contour Advance® Depth Gauge | Z179994 | – | – |
| Depth Gauge (Straight) | Z60006 | – | – |
| CI500 Series Sterile Silicone Implant Template* | S211296 | – | – |
| CI500 Series Non-Sterile Silicone Implant Template | Z179609 | – | – |
| Spacer for Intraoperative Testing | Z33012 | – | – |
| **Accessories** | | | |
| Non-Magnetic Cassette | P782484 | – | – |
| Replacement Magnet Cassette | P782485 | – | – |

* Supplied with implant; not available separately

Items used with the Cochlear Nucleus CI612 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, e.g. 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.

| Straight Electrode Claw | 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 implant magnet.

For more information see *MRI safety information* on page 55.

| Replacement Magnet Cassette | P782485 |
|---|---|


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

For more information see *MRI safety information* on page 55.

**Notes**

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


- When marking the incision site, the silicone carrier can be used as a template. For details see *Removing and replacing the magnet or non-magnetic cassette after implantation* on page 62.

| Depth Gauges | |
|---|---|
| Contour Advance Depth Gauge<br>Z179994 | Depth Gauge (Straight)<br>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*.

## CI500 Series Sterile Silicone Template S211296

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 see warnings below and *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 32.

**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 e.g. dropped or mishandled in theatre after removal from packaging.
- Use with CI500 and CI600 Series implants only.

# 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 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.

## Spacer for Intraoperative Testing Z33012

When the processor coil is placed directly over the implant coil, use the spacer to ensure there is enough distance between the coils.


**Warning**

Must be used in a sterile sheath. Use without a sterile sheath could cause infection.

# Notes

# Surgical procedure

The surgical procedure described in this guide is only one approach to implanting the Cochlear Nucleus CI612 cochlear implant.

The surgical procedure includes the following:

1. Pre-incision: non sterile field – page 31.
2. Opening the CI500 Series Sterile Silicone Implant Template – page 32.
3. Incision – page 33.
4. Mastoidectomy and preparing the bone recess – page 34.
5. Drilling tie down holes – page 37.
6. Opening the facial recess – page 38.
7. Preparing the cochleostomy – page 39.
8. Inspecting the cochlear implant and electrodes – page 41.
9. Positioning and securing the device – page 42.
10. Securing the extracochlear electrode – page 43.
11. Inserting the intracochlear electrode – page 44.
12. Securing and sealing the intracochlear electrode – page 47.
13. Performing intraoperative measurements – page 49.
14. Closure – page 50.

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments and accessories*** on page 36.

# 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.
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 CI500 Series Sterile Silicone Implant Template

One CI500 Series Sterile Silicone Implant Template is packaged with each implant. For more information on use of the template see ***CI500 Series Sterile Silicone Template*** on page 27.

### 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

1. 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.
2. 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, i.e. 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.

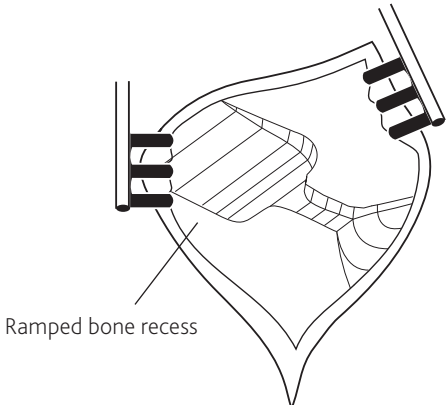
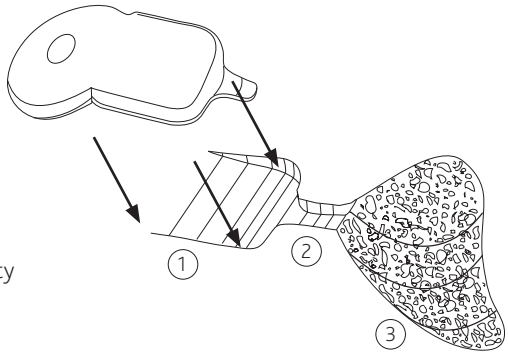



Figure 7: Ramped bone recess

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 8: 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 – see Figure 8. 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 (see *The bone recess* on page 34), 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 9: 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

This section describes site preparation. For details on inserting the electrode see *11. Inserting the intracochlear electrode* on page 44.

## 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.

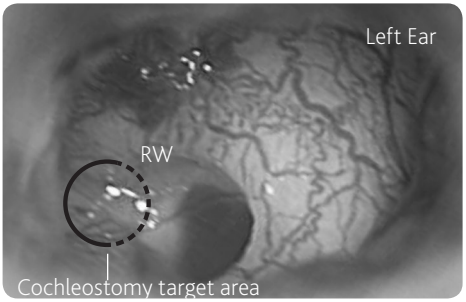



Figure 10: Cochleostomy target area

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 44.

# 8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked see *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 32.

**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 stylet 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/pericranial pocket between the tie-down holes.

   For information on correct implant orientation see *Device description* on page 17.

   **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**

   In case the magnet needs to be removed in future, do not suture directly over the magnet cassette cover – see *Figure 15* on page 58.

# 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**

- Damage to the electrode and the cochlea may be caused if the stylet is reinserted. Do not reinsert the stylet in order to reinsert or reposition the electrode.
- 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.

**Note**

At the end of the insertion, the most proximal rib is usually just outside the cochleostomy. Do not force the electrode into the cochlea.

## 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.

## Advance Off-Stylet® (AOS™) insertion

The AOS method, as described, is highly recommended by Cochlear. The AOS method was developed specifically for implants with the Contour Advance Electrode.

1. Grasp the protective tube (in the end section) and carefully remove the tube from the electrode. Do not squeeze, stretch or bend the electrode.
2. Orientate the electrode so that its curve will follow the cochlear spiral.
3. Guide the tip toward the cochleostomy, using the claw or other blunt tip surgical instrument. Angle the electrode toward the floor of the scala tympani. Ensure the half-band electrode contacts remain oriented toward the modiolus.
4. Insert the electrode until the white marker (7.6 mm from tip) is at the cochleostomy (see Figure 11 below).
5. Hold the stylet stationary with jeweller's forceps and hold the electrode at the ribs with AOS forceps. Advance the electrode off the stylet and into the cochlea until the third (most proximal) rib is at the cochleostomy (Figures B, C and D).
6. Remove the remainder of the stylet. Then pass the stylet out of the surgical field.

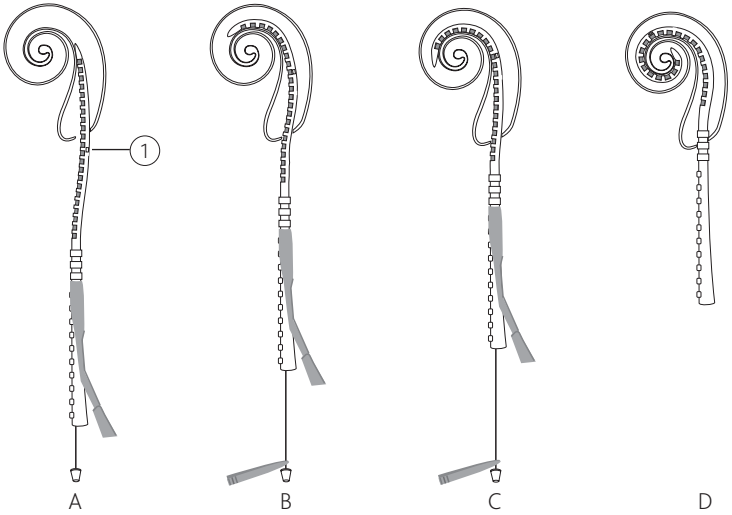



Figure 11: AOS Insertion (white marker (1) (7.6 mm from tip) at cochleostomy)

7. If necessary, retract the electrode slightly, so the third (most proximal) rib is just outside the cochleostomy. This ensures the electrode is close to the modiolus at the back of the basal turn.

# 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 in place continuously.

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 with an autograft consisting of strips of fascia or pericranium to ensure there are no gaps in the seal.

   **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 see 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. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

1. Replace the flap.
2. Put the processor coil and cable in a sterile sheath.

**Warning**

To avoid infection, if using the Intraoperative Spacer place the coil on top of the Intraoperative Spacer in the sterile sheath.

3. Place the external coil over the implant magnet.

**Note**

- The transmitting range of the cochlear implant is 1 mm to 10 mm. However, a maximum skin flap thickness of 6 mm to 9 mm is 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.

# Notes

# 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 three to four weeks after the operation. 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 identification card

Fill out the implant model number and ear details on the patient identification card. Give the card to the patient or their carer.

The patient or their carer should carry the patient identification 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. See *Cutting the intracochlear electrode lead* on page 54.
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 device without damage, cut the electrode lead before the ribbed portion of the array:

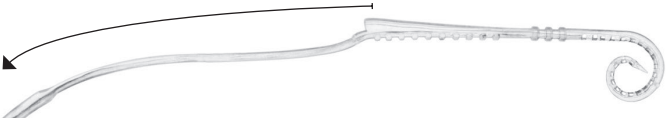


Figure 12: Contour Advance electrode lead cut location for explantation

If necessary, leave the distal end of the extracochlear electrode lead in place.

# Reporting problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

# MRI safety information


The Cochlear Nucleus CI612 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.


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

## Removing the magnet

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

Before MRI, in some instances the implant magnet cassette must be removed in a sterile surgical environment. If single or multiple MRI examinations on the head are needed with the magnet removed, replace the implant magnet 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 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 is removed, the recipient must wear a retainer disc to hold their sound processor coil in place. Retainer discs are available from Cochlear.

## Replacement magnet and non-magnetic cassettes

**Warning**

To avoid implant damage during MRI 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.


Figure 13: Nucleus Replacement Magnet Cassette – P782485


Figure 14: Nucleus Non-Magnetic Cassette – P782484

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

## Removing the magnet before implantation

If an MRI 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: CI612 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

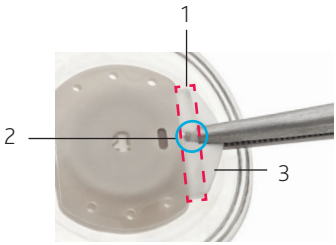



Figure 16: Forceps position on CI612 magnet cassette cover

**Caution**

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

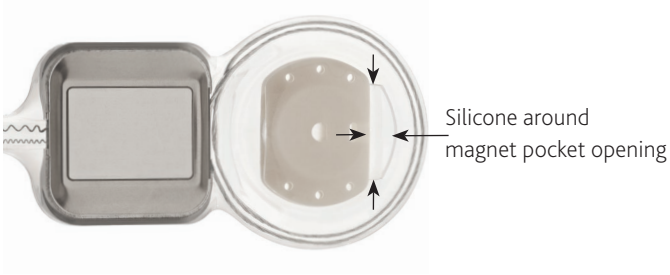



Figure 17: CI612 implant with magnet cassette removed

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 – see arrow in *Figure 18*.

**Caution**

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

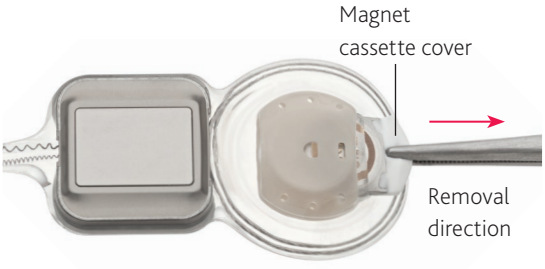



Figure 18: CI612 implant with magnet cassette partially removed

**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: CI612 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.

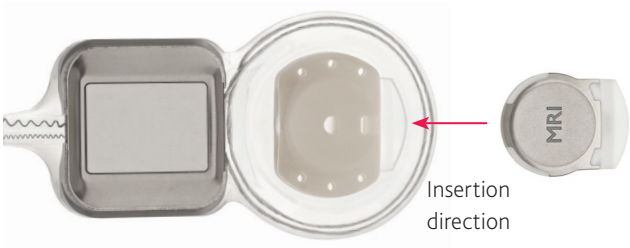



Figure 21: Non-magnetic cassette insertion direction

6. Ensure the non-magnetic cassette is fully inserted into the magnet pocket and the 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 or non-magnetic cassette after implantation* on page 62.

## Removing and replacing the magnet 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, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

Remove the magnet 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:

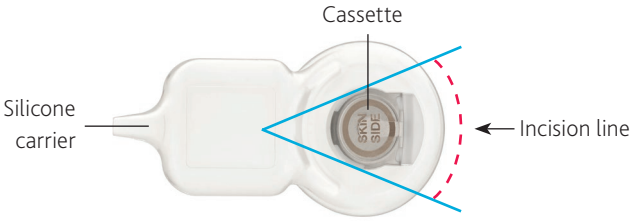



Figure 22: Marking the incision using the silicone carrier

2. Cut through any fibrous growth around the implant, exposing the distal end of the implant coil and the magnet cassette cover. Ensure there is good visibility and access to the magnet 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 magnet cassette cover.

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

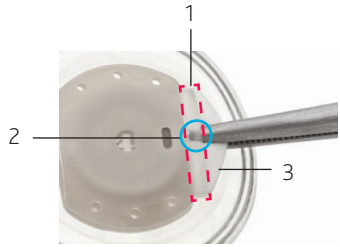



Figure 23: Forceps position on CI612 magnet cassette cover

5. Using constant traction, remove the magnet cassette from the magnet pocket. The removal direction is in the same plane as the implant coil, towards the distal end of the implant – see arrow in *Figure 24*.

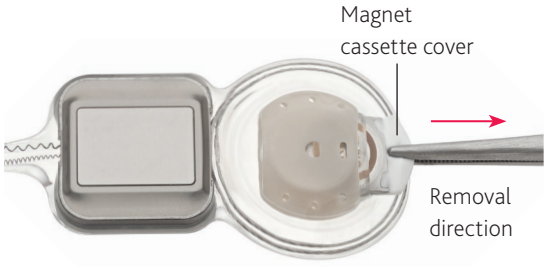



Figure 24: CI612 implant with magnet cassette partially removed

**Note**

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

Figure 25: Metal tab on magnet cassette


Figure 26: CI612 implant magnet cassette removal using metal tab

6. Dispose of the removed magnet cassette. It is 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 – see *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).

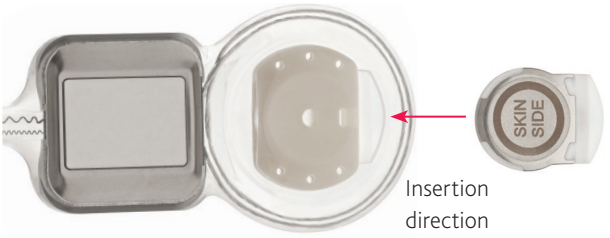



Figure 27: Replacement magnet cassette insertion direction

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 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.

# Notes

# 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 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

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

# CI612 implant specifications

| Intracochlear electrodes | |
|---|---|
| Number of electrodes | 22 electrodes |
| Distance between centre of electrode contacts | 0.8 mm at proximal end of array graduating to 0.4 mm at distal end of array when curled |
| Diameter of electrodes (cross-sectional dimension) | 0.8 mm at proximal end, tapering to 0.5 mm at distal end |
| Contact surface area | 0.21 $mm^2$ to 0.23 $mm^2$ |
| Active array length when straightened | 14.25 mm |
| Nominal electrode length when straightened | 19 mm from tip to proximal rib |
| Lead length | 99 mm from receiver/stimulator to array tip |
| Marker for insertion depth | White marker in middle of active part of array (lateral side) when tip is near lateral wall of otic capsule at back of basal turn |

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

| Receiver/Stimulator | |
|---|---|
| Dimensions | Case: 24 mm x 23 mm x 3.9 mm<br>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 to 10 mm (6 mm to 9 mm maximum skin flap thickness required for good magnet retention) |

| 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, bipolar 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<br>Magnet cassette cover<br>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.

## Symbols

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

Fragile, handle with care

Do not use if package is damaged

Refer to instruction manual

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

| | |
|---|---|
|  | Temperature limits |
|  | Keep dry |
| STERILE EO | Sterilised using ethylene oxide |
| Rx Only | Caution: US law restricts this device to sale by, or on the order of, a physician |
| REF | Catalogue number |
| SN | Serial number |
| LOT | Batch code |
| EC REP | Authorised representative in the European Community |
| CE | CE registration mark |
|  | MR Conditional |
| 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 |

# Hear now. And always

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Cochlear®

CI622

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

Physician's Guide

United States of America

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 (e.g. deep brain stimulators) and magnetic ventricular shunts, as the magnets may affect the function of these devices. The maximum magnetic field strength at one inch (1.0") from the edge of the implant coil (in the plane covering the surface of the head), is less than 300 Gauss.
- To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist 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. See *MRI safety information* on page 55.

## Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, electrode lead, or exposed magnet cassette cover.
- **Ionizing radiation therapy** can cause damage to the implant. Do not use ionizing 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 of the auditory nerve.

### Adults

Cochlear Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

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

# Contraindications

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

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlear development
- tympanic membrane perforation in the presence of active middle ear disease.

# 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

# Summary of adverse events

The following information summarizes adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant.

## 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/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

## Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

### Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

### Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

### Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

## Loss of residual hearing

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

# 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 system.

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

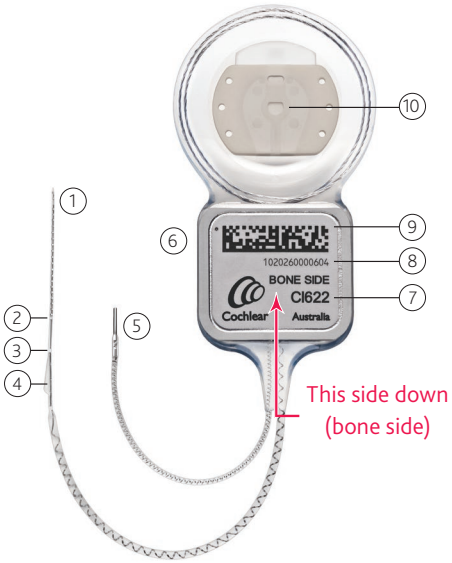
# New features

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.

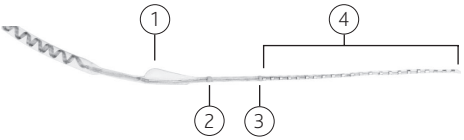



1 Intracochlear electrode
2 White marker indicating 20 mm insertion depth
3 White marker indicating 25 mm (max) insertion depth
4 Handle
5 Extracochlear electrode
6 Receiver/stimulator (printed information on bone side)
7 Model name
8 Serial number
9 Barcode
10 Implant coil plate with magnet cassette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

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

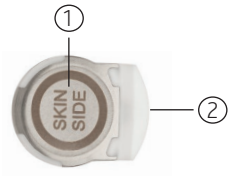

1 Implant coil plate with magnet cassette in pocket
2 Extracochlear electrode (plate) to face upwards/skin
3 Intracochlear electrode

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 Nucleus 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 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 Instrument Kit | CI500 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 | ✓ | – |
| Straight Electrode Claw | Z30090 | – | – |
| Contour Advance® Depth Gauge | Z179994 | – | – |
| Depth Gauge (Straight) | Z60006 | – | – |
| CI500 Series Sterile Silicone Implant Template* | S211296 | – | – |
| CI500 Series Non-Sterile Silicone Implant Template | Z179609 | – | – |
| Spacer for Intraoperative Testing | Z33012 | – | – |
| **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, e.g. 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.

| Straight Electrode Claw | 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 implant magnet.

For more information see *MRI safety information* on page 55.

| Replacement Magnet Cassette | P782485 |
|---|---|


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

For more information see *MRI safety information* on page 55.

**Notes**

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


- When marking the incision site, the silicone carrier can be used as a template. For details see *Removing and replacing the magnet or non-magnetic cassette after implantation* on page 62.

| Depth Gauges | |
|---|---|
| Contour Advance Depth Gauge<br>Z179994 | Depth Gauge (Straight)<br>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*.

## CI500 Series Sterile Silicone Template S211296

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 see warnings below and *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 32.

**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 e.g. dropped or mishandled in theatre after removal from packaging.
- Use with CI500 and CI600 Series implants only.

# 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 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.

## Spacer for Intraoperative Testing — Z33012

When the processor coil is placed directly over the implant coil, use the spacer to ensure there is enough distance between the coils.


**Warning**

Must be used in a sterile sheath. Use without a sterile sheath could cause infection.

# Notes

# 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 31.
2. Opening the CI500 Series Sterile Silicone Implant Template – page 32.
3. Incision – page 33.
4. Mastoidectomy and preparing the bone recess – page 34.
5. Drilling tie down holes – page 37.
6. Opening the facial recess – page 38.
7. Preparing the cochleostomy – page 39.
8. Inspecting the cochlear implant and electrodes – page 42.
9. Positioning and securing the device – page 43.
10. Securing the extracochlear electrode – page 44.
11. Inserting the intracochlear electrode – page 45.
12. Securing and sealing the intracochlear electrode – page 47.
13. Performing intraoperative measurements – page 49.
14. Closure – page 50.

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments and accessories*** on page 21.

# 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.
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 CI500 Series Sterile Silicone Implant Template

One CI500 Series Sterile Silicone Implant Template is packaged with each implant. For more information on use of the template see ***CI500 Series Sterile Silicone Template*** on page 27.

### 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

1. 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.
2. 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, i.e. 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.

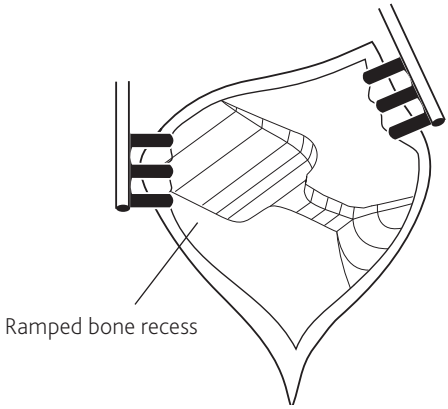
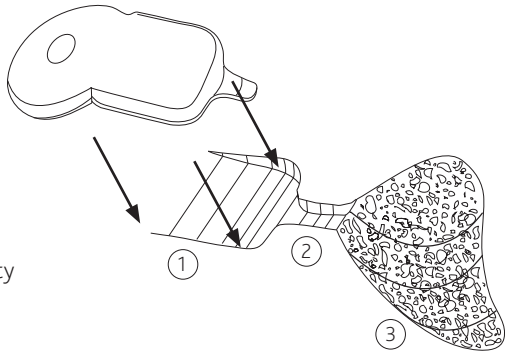



Figure 6: Ramped bone recess

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 – see Figure 7. 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 (see *The bone recess* on page 34), 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 see *11. Inserting the intracochlear electrode* on page 45.

## 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.

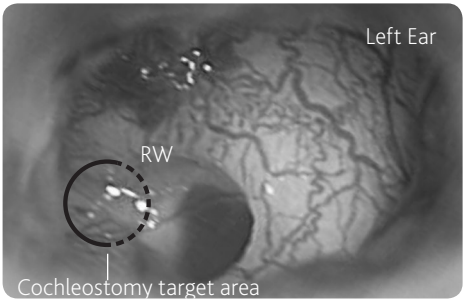



Figure 9: Cochleostomy target area

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 45.

## 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.

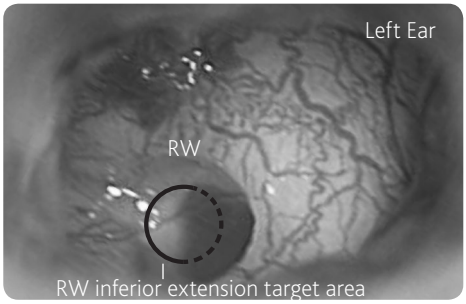



Figure 10: Round window target area

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 44.

# 8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked see *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 32.

**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/pericranial pocket between the tie-down holes.

   For information on correct implant orientation see *Device description* on page 17.

   **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**

   In case the magnet needs to be removed in future, do not suture directly over the magnet cassette cover – see *Figure 15* on page 58.

# 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.

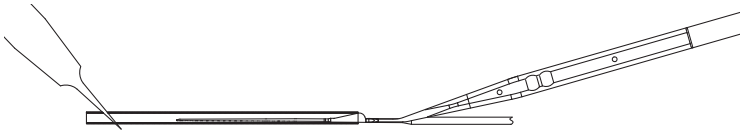


Figure 11: Removing the tube

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.

   **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 see 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. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

1. Replace the flap.
2. Put the processor coil and cable in a sterile sheath.

**Warning**

To avoid infection, if using the Intraoperative Spacer place the coil on top of the Intraoperative Spacer in the sterile sheath.

3. Place the external coil over the implant magnet.

**Note**

- The transmitting range of the cochlear implant is 1 mm to 10 mm. However, a maximum skin flap thickness of 6 mm to 9 mm is 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.

# Notes

# 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 three to four weeks after the operation. 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 identification card

Fill out the implant model number and ear details on the patient identification card. Give the card to the patient or their carer.

The patient or their carer should carry the patient identification 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. See *Cutting the intracochlear electrode lead* on page 54.
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 problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

# 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.


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

## Removing the magnet

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

Before MRI, in some instances the implant magnet cassette must be removed in a sterile surgical environment. If single or multiple MRI examinations on the head are needed with the magnet removed, replace the implant magnet 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 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 is removed, the recipient must wear a retainer disc to hold their sound processor coil in place. Retainer discs are available from Cochlear.

## Replacement magnet and non-magnetic cassettes

**Warning**

To avoid implant damage during MRI 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.


Figure 13: Nucleus Replacement Magnet Cassette – P782485


Figure 14: Nucleus Non-Magnetic Cassette – P782484

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

## Removing the magnet before implantation

If an MRI 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

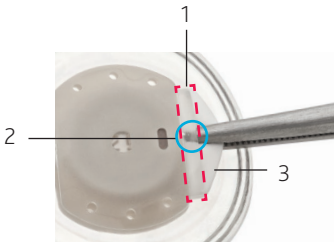



Figure 16: Forceps position on CI622 magnet cassette cover

**Caution**

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

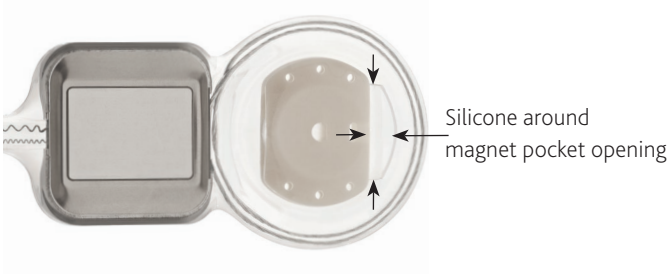



Figure 17: CI622 implant with magnet cassette removed

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 – see arrow in *Figure 18*.

**Caution**

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

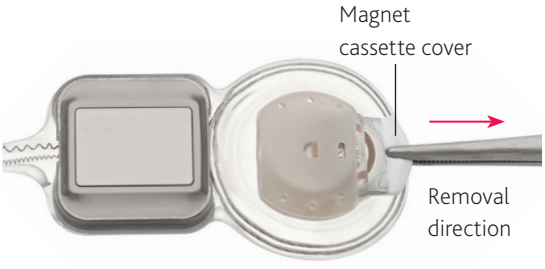



Figure 18: CI622 implant with magnet cassette partially removed

**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.

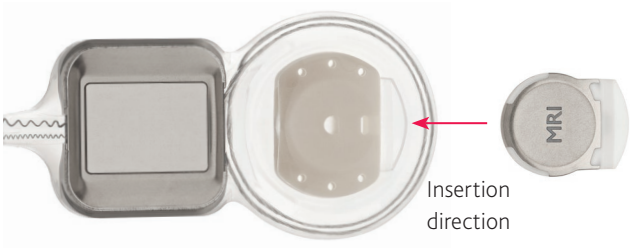



Figure 21: Non-magnetic cassette insertion direction

6. Ensure the non-magnetic cassette is fully inserted into the magnet pocket and the 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 or non-magnetic cassette after implantation* on page 62.

## Removing and replacing the magnet 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, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

Remove the magnet 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:

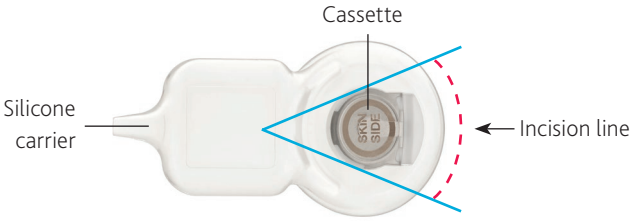



Figure 22: Marking the incision using the silicone carrier

2. Cut through any fibrous growth around the implant, exposing the distal end of the implant coil and the magnet cassette cover. Ensure there is good visibility and access to the magnet 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 magnet cassette cover.

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

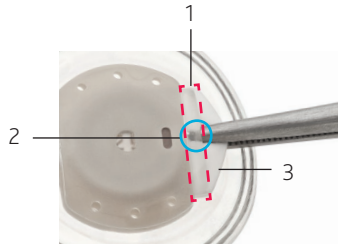



Figure 23: Forceps position on CI622 magnet cassette cover

5. Using constant traction, remove the magnet cassette from the magnet pocket. The removal direction is in the same plane as the implant coil, towards the distal end of the implant – see arrow in *Figure 24*.

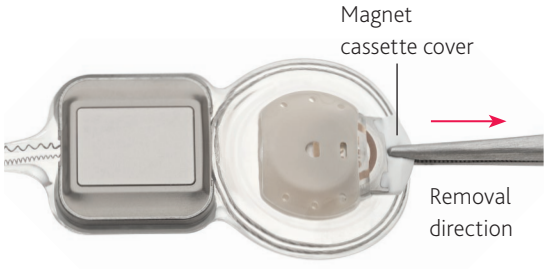



Figure 24: CI622 implant with magnet cassette partially removed

**Note**

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

Figure 25: Metal tab on magnet cassette


Figure 26: CI622 implant magnet cassette removal using metal tab

6. Dispose of the removed magnet cassette. It is 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 – see *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).

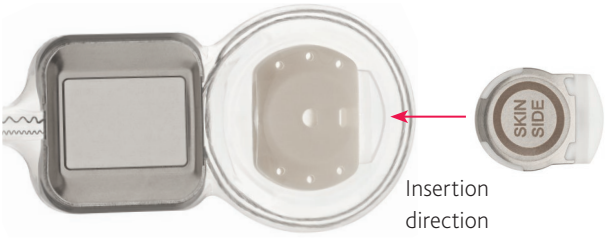



Figure 27: Replacement magnet cassette insertion direction

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 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.

# Notes

# 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 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

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

# 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<br>• 25 mm from tip to proximal marker |
| Lead length from receiver/ stimulator to array tip | 105 mm |

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

| Receiver/Stimulator | |
|---|---|
| Dimensions | Case: 24 mm x 23 mm x 3.9 mm<br>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 to 10 mm (6 mm to 9 mm maximum skin flap thickness required for good magnet retention) |

| 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, bipolar 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<br>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.

## Symbols

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

Fragile, handle with care

Do not use if package is damaged

Refer to instruction manual

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

| | |
|---|---|
|  | Temperature limits |
|  | Keep dry |
| STERILE EO | Sterilised using ethylene oxide |
| Rx Only | Caution: US law restricts this device to sale by, or on the order of, a physician |
| REF | Catalogue number |
| SN | Serial number |
| LOT | Batch code |
| EC REP | Authorised representative in the European Community |
| CE | CE registration mark |
|  | MR Conditional |
| 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 |

Hear now. And always

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Cochlear®

CI624

# Cochlear™ Nucleus® CI624 cochlear implant with Slim 20 electrode

Physician's Guide

United States of America

Hear now. And always

Cochlear®

# About this guide

**This guide applies to the Cochlear™ Nucleus® CI624 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.*
- To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist 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 CI624 implant is **MR Conditional**. MRI is contraindicated except under specific circumstances. See *MRI safety information* on page 57.

## Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, electrode lead, or exposed magnet cassette cover.
- **Ionizing radiation therapy** can cause damage to the implant. Do not use ionizing 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 of the auditory nerve.

### Adults

Cochlear Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

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

# Contraindications

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

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlear development
- tympanic membrane perforation in the presence of active middle ear disease.

# 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

# Summary of adverse events

The following information summarizes adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant.

## 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/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

## Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

### Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

### Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

### Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

## Loss of residual hearing

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

# 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 system.

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

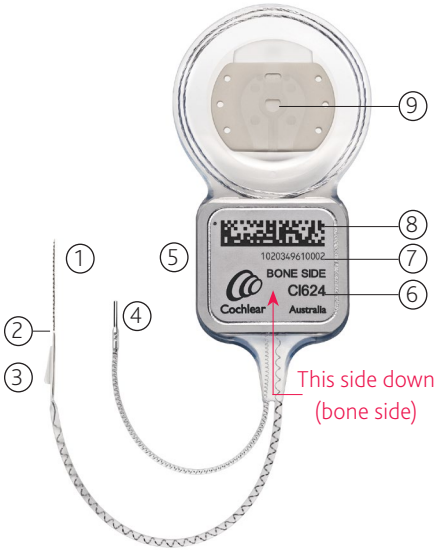
# New features

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: CI624 cochlear implant with magnet cassette partially removed from pocket

# The Cochlear™ Nucleus® CI624 cochlear implant with Slim 20 electrode

The CI624 implant is a CI600 Series implant.

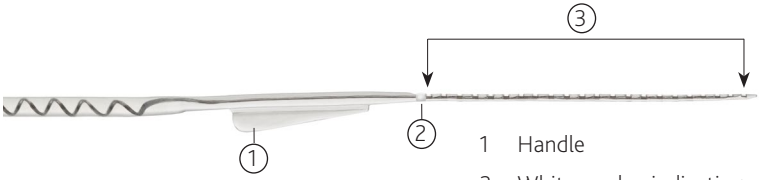



1 Intracochlear electrode
2 White marker indicating 20 mm insertion depth
3 Handle
4 Extracochlear electrode
5 Receiver/stimulator (printed information on bone side)
6 Model name
7 Serial number
8 Barcode
9 Implant coil with magnet

Figure 2: CI624 cochlear implant with Slim 20 electrode (bone side)


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

Figure 3: CI624 cochlear implant with Slim 20 electrode (skin side)

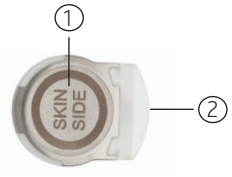



1 Handle

2 White marker indicating 20 mm active array

3 Intracochlear electrode with 22 half-band contacts (distal end gently curves away from the handle)

Figure 4: Slim 20 electrode




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

2 Magnet cassette cover

Figure 5: Cochlear Nucleus 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 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 Instrument Kit | CI500 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 | ✓ | – |
| Straight Electrode Claw | Z30090 | – | – |
| Contour Advance® Depth Gauge | Z179994 | – | – |
| Depth Gauge (Straight) | Z60006 | – | – |
| CI500 Series Sterile Silicone Implant Template* | S211296 | – | – |
| CI500 Series Non-Sterile Silicone Implant Template | Z179609 | – | – |
| Spacer for Intraoperative Testing | Z33012 | – | – |
| **Accessories** | | | |
| Non-Magnetic Cassette | P782484 | – | – |
| Replacement Magnet Cassette | P782485 | – | – |

* Supplied with implant; not available separately

Items used with the Cochlear Nucleus CI624 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, e.g. 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.

| Straight Electrode Claw | 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 implant magnet.<br><br>For more information see *MRI safety information* on page 57. |

| Replacement Magnet Cassette | P782485 |
|---|---|
|  | Used to replace a non-magnetic cassette after MRI examinations are complete.<br><br>For more information see *MRI safety information* on page 57. |

**Notes**

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


- When marking the incision site, the silicone carrier can be used as a template. For details see *Removing and replacing the magnet or non-magnetic cassette after implantation* on page 64.

| Depth Gauges | |
|---|---|
| Contour Advance Depth Gauge<br>Z179994 | Depth Gauge (Straight)<br>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*.

## CI500 Series Sterile Silicone Template S211296

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 see warnings below and *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 32.

**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 e.g. dropped or mishandled in theatre after removal from packaging.
- Use with CI500 and CI600 Series implants only.

# 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 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.

## Spacer for Intraoperative Testing — Z33012

When the processor coil is placed directly over the implant coil, use the spacer to ensure there is enough distance between the coils.


**Warning**

Must be used in a sterile sheath. Use without a sterile sheath could cause infection.

# Notes

# Surgical procedure

The surgical procedure described in this guide is only one approach to implanting the Cochlear Nucleus CI624 cochlear implant.

The surgical procedure includes the following:

1. Pre-incision: non sterile field – page 31.
2. Opening the CI500 Series Sterile Silicone Implant Template – page 32.
3. Incision – page 33.
4. Mastoidectomy and preparing the bone recess – page 34.
5. Drilling tie down holes – page 37.
6. Opening the facial recess – page 38.
7. Preparing the cochleostomy – page 39.
8. Inspecting the cochlear implant and electrodes – page 42.
9. Positioning and securing the device – page 43.
10. Securing the extracochlear electrode – page 44.
11. Inserting the intracochlear electrode – page 45.
12. Securing and sealing the intracochlear electrode – page 48.
13. Performing intraoperative measurements – page 50.
14. Closure – page 51.

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments and accessories*** on page 23.

# 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.
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 CI500 Series Sterile Silicone Implant Template

One CI500 Series Sterile Silicone Implant Template is packaged with each implant. For more information on use of the template see ***CI500 Series Sterile Silicone Template*** on page 29.

### 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

1. 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.
2. 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, i.e. 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.

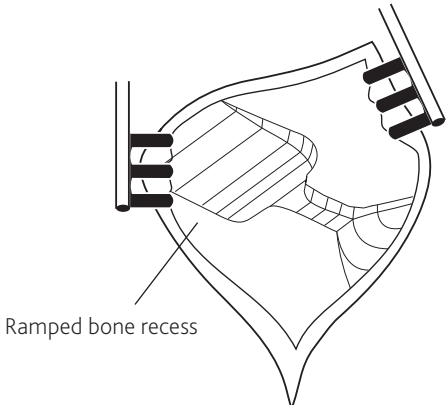
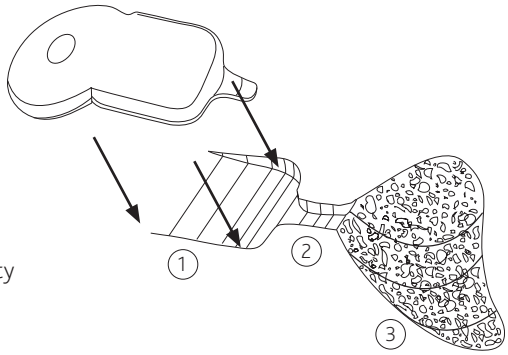



Figure 6: Ramped bone recess

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 – see Figure 7. 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 (see *The bone recess* on page 34), 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 CI624 cochlear implant with Slim 20 electrode is compatible with both round window and cochleostomy approaches.

This section describes site preparation for both approaches. For details on inserting the electrode see *11. Inserting the intracochlear electrode* on page 45.

## 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.

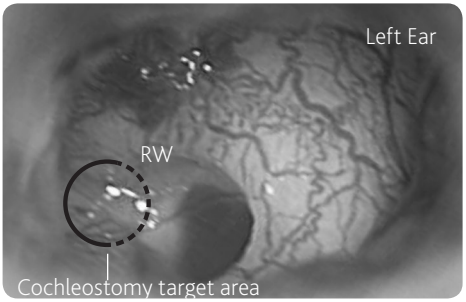



Figure 9: Cochleostomy target area

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 45.

## 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.

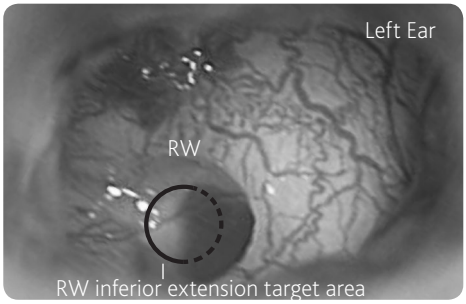



Figure 10: Round window target area

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 45.

# 8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked see *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 32.

**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 wires inside are 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/pericranial pocket between the tie-down holes.

   For information on correct implant orientation see *Device description* on page 17.

   **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 – see *Figure 15* on page 60.

# 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

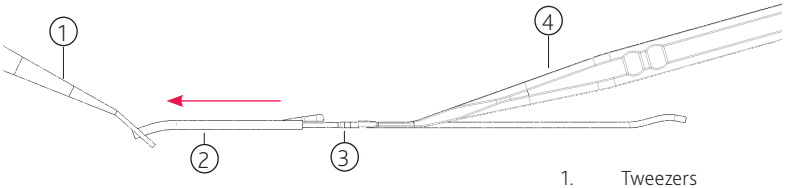
Make a straight incision the width of the round window.

## Insertion

**Note**

To prevent movement of the electrode in the cochlea before the insertion, ensure the lead is not twisted or coiled.

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




1. Tweezers
2. Protective tube
3. Electrode
4. Tweezers

Figure 11: Removing the tube

2. Guide the tip of the array toward the cochleostomy or round window using AOS forceps (or similar surgical tweezers) 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 handle remains oriented inferiorly (away from the modiolus). The handle is located on the opposite side of the electrode contacts. The electrode contacts are to remain oriented towards the modiolus.

**Warning**

Do not force if resistance is felt before full insertion

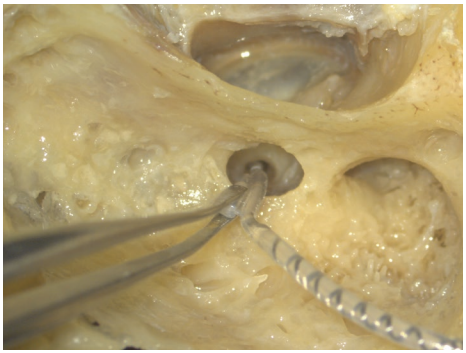


Figure 12: Electrode insertion with handle oriented inferiorly (away from the modiolus)

4. Continue inserting the electrode to a suitable depth using the white marker located at 20 mm on the electrode as a guide.

   The maximum recommended insertion depth is 20 mm. It is not necessary to insert the electrode to the maximum depth of 20 mm. Partial insertion is better than forcing the electrode beyond the point of first resistance.

5. Continue to hold the array in position with the forceps.

**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.

# 12. Securing and sealing the intracochlear electrode

1. Whilst continuing to hold the electrode in place, stabilise the electrode array to minimise movement inside the cochlea.

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

   **Note**

   If the electrode leads 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.

2. Coil the excess proximal electrode lead inside the mastoid cavity under the bony overhangs. 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.

3. Place any excess loop of the extracochlear electrode in the mastoid cavity.

## 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 see 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. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

1. Replace the flap.
2. Put the processor coil and cable in a sterile sheath.

   **Warning**

   To avoid infection, if using the Intraoperative Spacer place the coil on top of the Intraoperative Spacer in the sterile sheath.

3. Place the external coil over the implant magnet.

   **Note**

   - The transmitting range of the cochlear implant is 1 mm to 10 mm. However, a maximum skin flap thickness of 6 mm to 9 mm is 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.

# Notes

# 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 three to four weeks after the operation. 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 identification card

Fill out the implant model number and ear details on the patient identification card. Give the card to the patient or their carer.

The patient or their carer should carry the patient identification 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. See *Cutting the intracochlear electrode lead* on page 56.
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 13: Slim 20 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 problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

# MRI safety information


The Cochlear Nucleus CI624 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.


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

## Removing the magnet

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

Before MRI, in some instances the implant magnet cassette must be removed in a sterile surgical environment. If single or multiple MRI examinations on the head are needed with the magnet removed, replace the implant magnet 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 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 is removed, the recipient must wear a retainer disc to hold their sound processor coil in place. Retainer discs are available from Cochlear.

## Replacement magnet and non-magnetic cassettes

**Warning**

To avoid implant damage during MRI 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.


Figure 14: Nucleus Replacement Magnet Cassette – P782485


Figure 15: Nucleus Non-Magnetic Cassette – P782484

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

## Removing the magnet before implantation

If an MRI 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 16: CI624 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

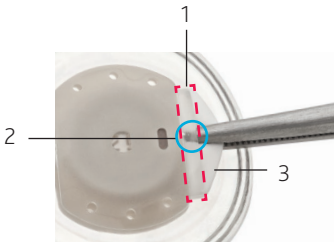



Figure 17: Forceps position on CI624 magnet cassette cover

**Caution**

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

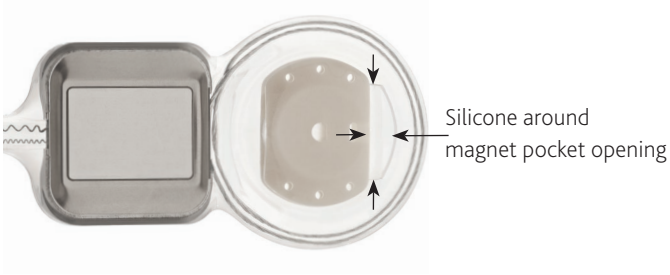



Figure 18: CI624 implant with magnet cassette removed

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 – see arrow in *Figure 19*.

**Caution**

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

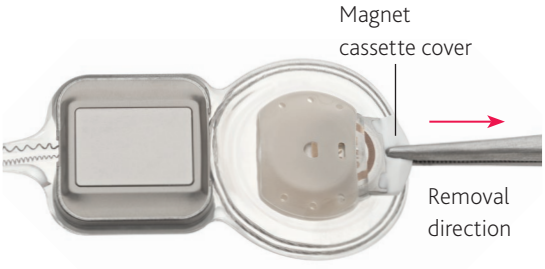



Figure 19: CI624 implant with magnet cassette partially removed

**Note**

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

Figure 20: Metal tab on magnet cassette


Figure 21: CI624 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.

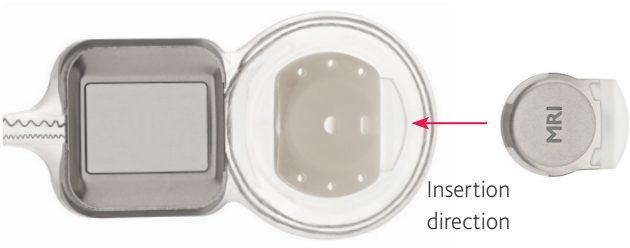



Figure 22: Non-magnetic cassette insertion direction

6. Ensure the non-magnetic cassette is fully inserted into the magnet pocket and the 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 or non-magnetic cassette after implantation* on page 64.

## Removing and replacing the magnet 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, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

### Note

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

Remove the magnet 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:

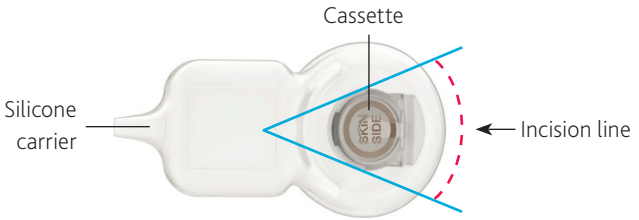



Figure 23: Marking the incision using the silicone carrier

2. Cut through any fibrous growth around the implant, exposing the distal end of the implant coil and the magnet cassette cover. Ensure there is good visibility and access to the magnet 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 magnet cassette cover.

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

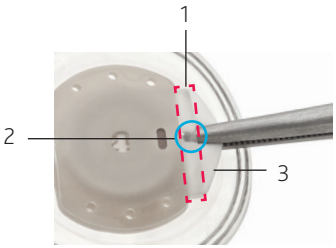



Figure 24: Forceps position on CI624 magnet cassette cover

5. Using constant traction, remove the magnet cassette from the magnet pocket. The removal direction is in the same plane as the implant coil, towards the distal end of the implant – see arrow in *Figure 25*.

**Note**

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

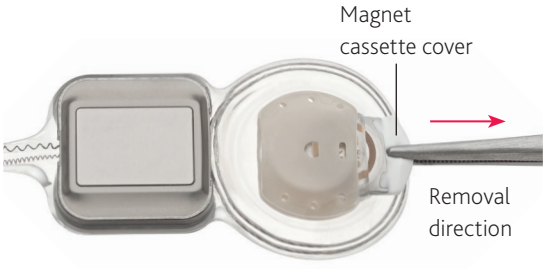



Figure 25: CI624 implant with magnet cassette partially removed

**Note**

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

Figure 26: Metal tab on magnet cassette


Figure 27: CI624 implant magnet cassette removal using metal tab

6. Dispose of the removed magnet cassette. It is 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 – see *Figure 28* 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).

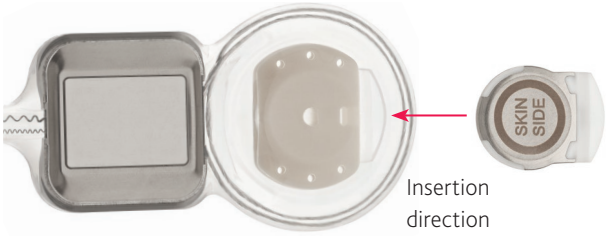



Figure 28: Replacement magnet cassette insertion direction

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 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.

# Notes

# 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 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

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

# CI624 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 marker |
| Lead length from receiver/ stimulator to array tip | 105 mm |

| Extracochlear electrodes |
|---|
| • Plate on receiver/stimulator<br>• 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<br>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 to 10 mm (6 mm to 9 mm maximum skin flap thickness required for good magnet retention) |

| 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, bipolar 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<br>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.

## Symbols

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

Fragile, handle with care

Do not use if package is damaged

Refer to instruction manual

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

| | |
|---|---|
|  | Temperature limits |
|  | Keep dry |
|  | Sterilised using ethylene oxide |
| Rx Only | Caution: US law restricts this device to sale by, or on the order of, a physician |
|  | Catalogue number |
|  | Serial number |
|  | Batch code |
|  | Authorised representative in the European Community |
|  | CE registration mark |
|  | MR Conditional |
| 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 |

Hear now. And always

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Cochlear®

CI632

# Cochlear™ Nucleus® CI632 cochlear implant with Slim Modiolar electrode

Physician's Guide

United States of America

Hear now. And always

Cochlear®

# About this guide

**This guide applies to the Cochlear™ Nucleus® CI632 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 (e.g. deep brain stimulators) and magnetic ventricular shunts, as the magnets may affect the function of these devices. The maximum magnetic field strength at one inch (1.0") from the edge of the implant coil (in the plane covering the surface of the head), is less than 300 Gauss.
- To reduce the risk of anesthetic-related adverse events, a pediatric anesthesiologist 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 CI632 implant is **MR Conditional**. MRI is contraindicated except under specific circumstances. See *MRI safety information* on page 67.

## Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, electrode lead, or exposed magnet cassette cover.
- **Ionizing radiation therapy** can cause damage to the implant. Do not use ionizing 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 of the auditory nerve.

### Adults

Cochlear Nucleus cochlear implants are intended for use in individuals 18 years of age or older who have bilateral, pre, peri or postlinguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids.

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

Children two 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 three to six month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

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

# Contraindications

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

- deafness due to lesions of the acoustic nerve or central auditory pathway
- active middle ear infections
- absence of cochlear development
- tympanic membrane perforation in the presence of active middle ear disease.

# 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

# Summary of adverse events

The following information summarizes adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant.

## 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/surgical or device-related complication.

11 of the 20 complications were medical/surgical in nature and the remaining nine were device-related. 18 of the 20 adverse events resolved without surgical or extensive medical intervention.

### Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment. One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

### Device-related complications

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

## Children

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

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

A retrospective review of 84 children that were between 9 and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for the second clinical investigation. 24 patients experienced 28 medical/surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study.

### Medical/Surgical complications

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device. Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

Six patients experienced minor post-operative complications, four of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage peri-operatively. These were medically managed, which included one reimplantation. Two patients experienced post-operative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of post-operative meningitis.

### Device-related complications

No device failures or other serious device malfunctions were observed during the first study. 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 processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

For the second study, no device failures, device extrusions, or other serious device malfunctions were reported. Three patients experienced mild skin irritations. One of the irritations were resolved by decreasing the magnet strength and two resolved on their own. Electrode faults that were resolved with programming were not captured in this study, and there were no reports of untoward medical events or serious device malfunctions related to electrode faults.

### Adverse Events in Research Articles

As of February 2020, Cochlear performed a systematic literature review to assess safety of implantation with a Cochlear Nucleus Cochlear Implant in infants aged between 9 and 12 months. A multi-step literature search process resulted in a final a final set of studies 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 anesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and post-operative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

## Loss of residual hearing

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

# 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 system.

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

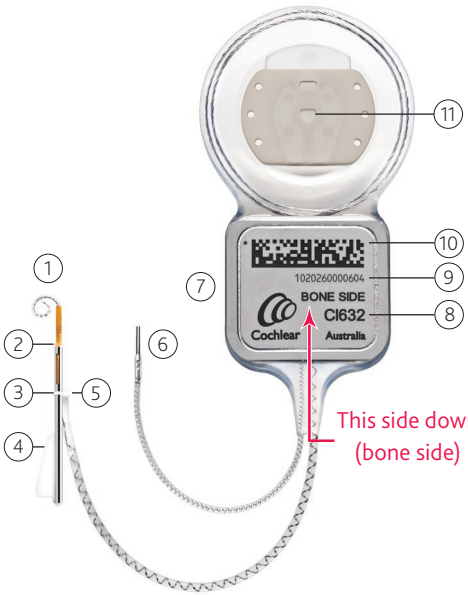
# New features

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: CI632 cochlear implant with magnet cassette partially removed from pocket

# The CI632 cochlear implant with Slim Modiolar electrode

The CI632 implant is a CI600 Series implant.

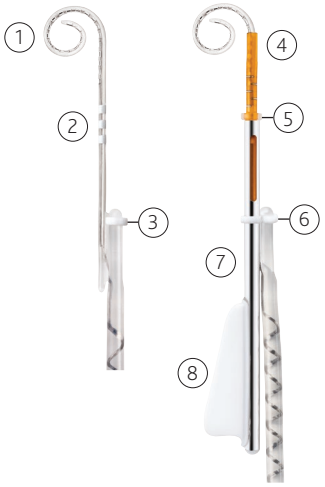



1 Intracochlear electrode
2 Sheath stopper
3 White alignment marker on sheath
4 Sheath handle
5 White alignment marker on intracochlear electrode
6 Extracochlear electrode
7 Receiver/stimulator (printed information on bone side)
8 Model name
9 Serial number
10 Barcode
11 Implant coil plate with magnet cassette in pocket

Figure 2: CI632 cochlear implant with Slim Modiolar electrode (bone side)

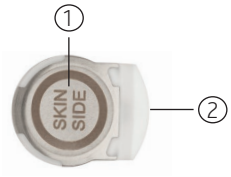

1 Implant coil plate with magnet cassette in pocket
2 Extracochlear electrode (plate) to face upwards/skin
3 Intracochlear electrode with sheath

Figure 3: CI632 cochlear implant with Slim Modiolar electrode (skin side)




1 Intracochlear electrode
2 Three white insertion depth markers, visible only after sheath is removed
3 White alignment marker on intracochlear electrode
4 Sheath tip
5 Sheath stopper
6 White alignment marker on sheath (when electrode is fully inserted, aligns with white alignment marker on electrode)
7 Sheath guide tube
8 Sheath handle

Figure 4: Slim Modiolar electrode with sheath removed and with sheath




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

Figure 5: Cochlear Nucleus 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 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 Instrument Kit | CI500 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 | ✓ | – |
| Straight Electrode Claw | Z30090 | – | – |
| Contour Advance® Depth Gauge | Z179994 | – | – |
| Depth Gauge (Straight) | Z60006 | – | – |
| CI500 Series Sterile Silicone Implant Template* | S211296 | – | – |
| CI500 Series Non-Sterile Silicone Implant Template | Z179609 | – | – |
| Spacer for Intraoperative Testing | Z33012 | – | – |
| Cochleostomy Sizing Tool* | S407840 | – | – |
| Slim Modiolar Electrode Sheath | P1291522 | – | – |
| **Accessories** | | | |
| Non-Magnetic Cassette | P782484 | – | – |
| Replacement Magnet Cassette | P782485 | – | – |

* Supplied with implant; not available separately

Items used with the Cochlear Nucleus CI632 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, e.g. 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.

| Straight Electrode Claw | 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 implant magnet.<br><br>For more information see *MRI safety information* on page 67. |

| Replacement Magnet Cassette | P782485 |
|---|---|
|  | Used to replace a non-magnetic cassette after MRI examinations are complete.<br><br>For more information see *MRI safety information* on page 67. |

**Notes**

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


- When marking the incision site, the silicone carrier can be used as a template. For details see *Removing and replacing the magnet or non-magnetic cassette after implantation* on page 74.

## Cochleostomy Sizing Tool S407840

1 Stopper – 1.4 mm diameter
2 Tip – 0.8 mm diameter


Packed in the implant tray (white seal).

Used to determine/check the size of the cochleostomy or round window, to confirm if the electrode with sheath will fit.

Using the sizing tool to test the opening confirms if the sheath stopper will prevent the sheath and electrode from advancing too far into the cochlea.

## Slim Modiolar Electrode Sheath P1291522

1 Sheath handle
2 White alignment marker
3 Stopper – 1.4 mm diameter
4 Sheath tip


Replacement sheath, used if the primary sheath is damaged or removed from the sterile field.

| Depth Gauges | |
|---|---|
| Contour Advance Depth Gauge<br>Z179994 | Depth Gauge (Straight)<br>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*.

## CI500 Series Sterile Silicone Template S211296

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 see warnings below and *2. Opening the CI500 Sterile Silicone Implant Template* on page 33.

**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 e.g. dropped or mishandled in theatre after removal from packaging.
- Use with CI500 and CI600 Series implants only.

# 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 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.

| Spacer for Intraoperative Testing | Z33012 |
|---|---|

When the processor coil is placed directly over the implant coil, use the spacer to ensure there is enough distance between the coils.


**Warning**

Must be used in a sterile sheath. Use without a sterile sheath could cause infection.

# Notes

# Surgical procedure

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

The surgical procedure includes the following:

1. Pre-incision: non-sterile field – page 32
2. Opening the CI500 Sterile Silicone Implant Template – page 33
3. Incision and periosteal pocket – page 34
4. Mastoidectomy and preparing the bone recess – page 35
5. Drilling tie-down holes – page 38
6. Opening the facial recess (Posterior Tympanotomy) – page 39
7. Preparing the round window or cochleostomy – page 40
8. Inspecting the implant, electrodes and sizing tool – page 44
9. Positioning and securing the implant – page 45
10. Securing the extracochlear electrode – page 46
11. Inserting the intracochlear electrode – page 47
12. Securing and sealing the intracochlear electrode – page 59
13. Performing intraoperative measurements – page 61
14. Closure – page 62

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments and accessories*** on page 21.

# 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.
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 CI500 Sterile Silicone Implant Template

One CI500 Series Sterile Silicone Implant Template is packaged with each implant. For warnings and more information see *CI500 Series Sterile Silicone Template* on page 28.

To open the template tray:

**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 and sizing tool displays the Cochlear logo and has a white seal.

   Warning

   If the sterile pack 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 and periosteal pocket

**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, i.e. 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.

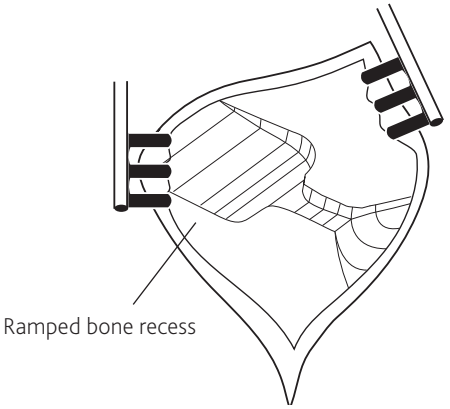
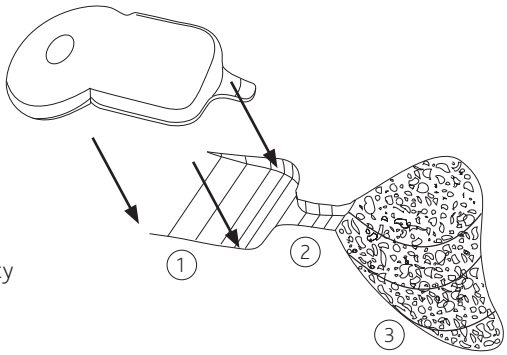



Figure 6: Ramped bone recess

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 — see *Figure 7*. 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 (see *The bone recess* on page 35), 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 (Posterior Tympanotomy)

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 round window or cochleostomy

The CI632 implant electrode is compatible with both the round window and cochleostomy approaches.

This section describes site preparation for both approaches. For details on inserting the electrode array see *11. Inserting the intracochlear electrode* on page 47.

**Caution**

The recommended cochlea opening is between 0.8 mm and 1.0 mm wide.

The Cochleostomy Sizing Tool can be used to check the size during drilling and the final size of the opening.

If the opening is larger than 1.4 mm, use the forceps holding the sheath handle to stabilise the sheath and ensure the stopper stays at the round window or cochleostomy opening.

**Warning**

Do not suction the perilymph.

## 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.

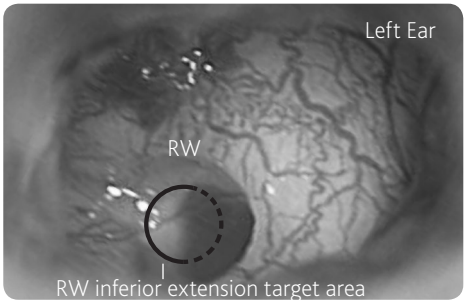



Figure 9: Round window target area

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 47.

## 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.
2. 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.
3. Perform a cochleostomy into the scala tympani using a diamond burr at low speed.
4. 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.

5. Drill sufficient bone to expose at least 0.8–1.0 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 47.

6. Remove the final layer of bone.

# 8. Inspecting the implant, electrodes and sizing tool

If the Sterile Silicone Implant Template is not unpacked see *2. Opening the CI500 Sterile Silicone Implant Template* on page 33.

1. Remove the implant tray (white seal) from the packaging.
2. Tear open the seal of the implant tray and check the tray contains an implant and a Cochleostomy Sizing Tool.
3. Remove the implant.
4. Confirm the implant is not damaged and the electrode is contained within the sheath.

**Warning**

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 damage to the cochlear implant:

- minimise handling of the electrode
- do not bend the electrode as it is malleable and will deform
- leave the sheath on the electrode until just after 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/pericranial pocket between the tie-down holes.

   For information on correct implant orientation see *Device description* on page 17.

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**

   In case the magnet needs to be removed in future, do not suture directly over the magnet cassette cover – see *Figure 24* on page 70.

# 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

## Before insertion

The following should be performed immediately before inserting the electrode.

### Round window

Make a straight incision the width of the round window.

### 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**

Do not suction the perilymph.

## Overview of insertion steps

Figure 10: Steps for inserting electrode into the cochlea

### Note

To prevent movement of the electrode in the cochlea:

- Before the insertion, ensure the lead is not twisted or coiled.
- Hold the sheath handle in forceps to introduce the electrode into the cochlea.
- Maintain hold and control of the electrode until it is fully inserted, the sheath is removed and the lead is stabilised.

### Caution

If resistance is felt during insertion, stop immediately, withdraw the sheath and assess the exposure of the round window/ cochleostomy opening. You should be able to advance the electrode without resistance. Do not use force.

### Warning

If the cochleostomy/round window incision is wider than 1.4 mm or significant resistance is felt during array insertion, use both hands to stabilise before continuing. This will help prevent the sheath stopper advancing through the opening.

## Insertion

To insert the intracochlear electrode into the cochlea:

A. Hold the sizing tool by the handle with AOS Forceps. Insert the sizing tool into the cochleostomy/round window opening until the silicone stopper reaches the cochlea opening. Ensure that the tip of the sizing tool easily enters the cochlea opening and the stopper doesn't advance through the opening.

   This is to check the cochlea opening width is between 0.8 mm and 1.0 mm.

B. Put the sizing tool down. Use blunt-nosed forceps with serrated tips to take hold of the electrode by the sheath handle.

C. Holding the sheath handle securely, use AOS Forceps to gently hold the electrode lead below the white alignment marker as shown. To straighten the intracochlear electrode, slowly retract the electrode until it is fully inside the sheath and resistance is encountered.

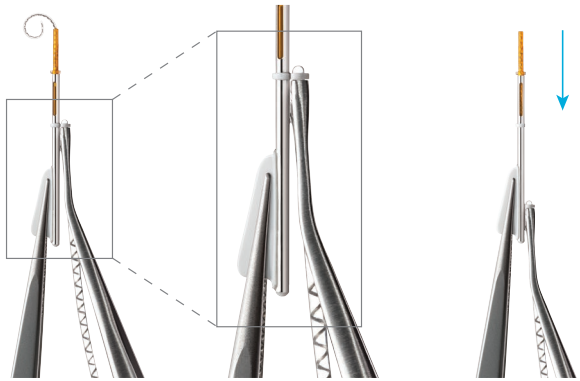


Figure 11: Straightening the intracochlear electrode

D. Hold the sheath handle with forceps and direct the sheath and electrode array towards the opening of the cochleostomy/ round window. Orientate the sheath handle toward the modiolus so the electrode curve follows the cochlea spiral, ensuring it is guided through the scala tympani with stimulating pads facing the modiolus. Guide the sheath into the cochlea until the sheath stopper reaches the cochleostomy/round window.

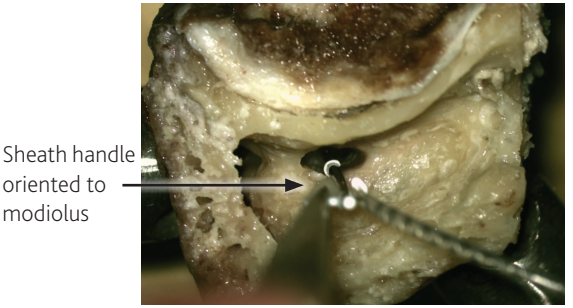



Figure 12: Inserting sheath tip into cochleostomy/round window opening (right ear temporal bone shown)

**Caution**

If resistance is felt during insertion, stop immediately, withdraw the sheath and assess the exposure of the round window/ cochleostomy opening. You should be able to insert the sheath to the stopper without resistance. Do not use force.

## Notes

- Ensure correct orientation of the electrode in the scala tympani.

  Use the white sheath handle as a guide for correct orientation. The handle should be orientated towards the modiolus and follow the plane of the scala tympani.

  If the handle is not aligned correctly, the electrode tip could move down towards the floor of the scala tympani or up towards the basilar membrane, meaning electrode placement will be sub-optimal with compromised positioning in the scala tympani.

  Be aware of the lead coiling from the electrode to receiver/ stimulator as this could also impact electrode direction.

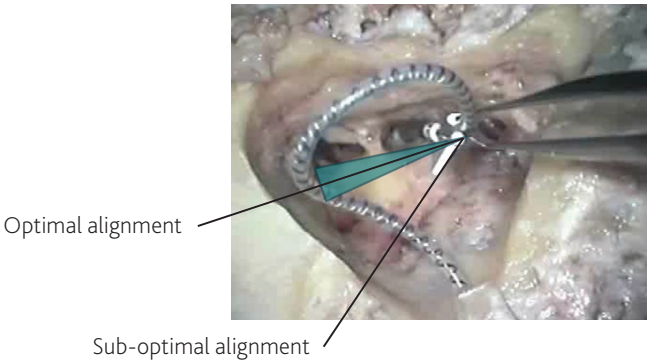



Figure 13: Aligning handle along medial plane of scala tympani

- Ensure the electrode remains in the sheath during insertion.

  During insertion, do not hold the electrode to insert the sheath up to the stopper.

  Hold only the sheath handle until the stopper is at the cochleostomy/round window entrance. Then use your other hand to advance the electrode through the sheath.

  This can prevent the electrode tip from prematurely advancing from the sheath before the stopper is correctly positioned against the cochlea opening.

Figure 14: Electrode tip visible from end of sheath before reaching cochleostomy entrance

**Warning**

- **Ensure the sheath stopper remains against the cochleostomy/round window opening.**

  Ensure the sheath stopper is at the cochleostomy/round window. If the electrode is advanced before the stopper reaches the cochleostomy/round window, the tip could fold over.

  If the cochleostomy/round window opening is too large, use AOS Forceps to hold the electrode and, with your other hand, use forceps to stabilise the sheath stopper at the entrance to prevent the stopper being pushed too far.

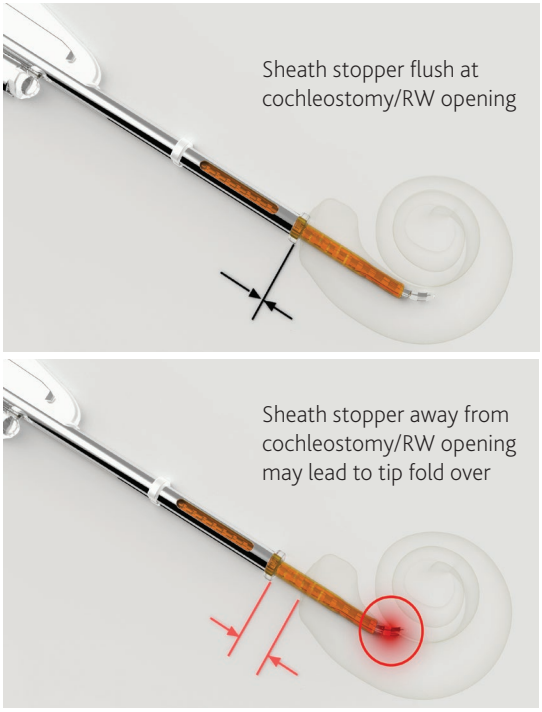



Figure 15: Sheath not flush at cochleostomy entrance may result in poor insertion

E. Continuing to hold the sheath handle, use AOS Forceps to grip the electrode lead behind the white marker. Use AOS Forceps to advance the electrode through the sheath guide tube until the white markers are aligned.

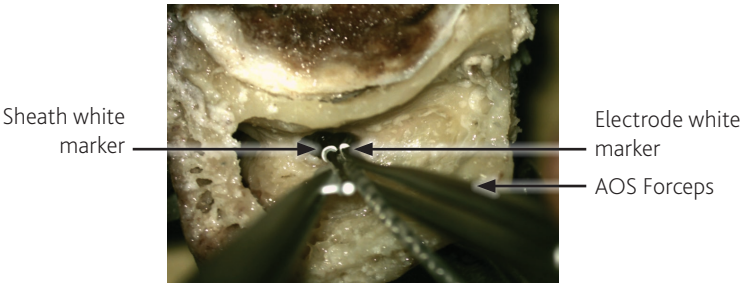



Figure 16: Advancing electrode into cochlea (right ear temporal bone shown)

The electrode array is now fully inserted into the cochlea but the sheath is still attached to the electrode lead.

**Caution**

If resistance is felt before full insertion, stop immediately and assess the trajectory and/or position of the sheath. You should be able to advance the electrode without resistance. Do not use force.

F. While continuing to hold the electrode lead with AOS Forceps, use forceps to slowly retract the sheath, sliding it straight back in line with the electrode array until completely disengaged.

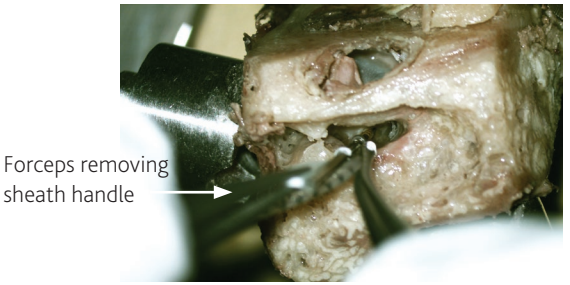



Figure 17: Removing sheath with forceps

G. The electrode is fully inserted in the cochlea with the sheath removed. The three white insertion depth markers can be used to confirm the inserted depth of the electrode. If the three markers are at the cochleostomy/round window opening, a full insertion has been performed.

Ensure the array is not pushed/advanced further into the cochlea to avoid over-insertion and compromised perimodiolar positioning.

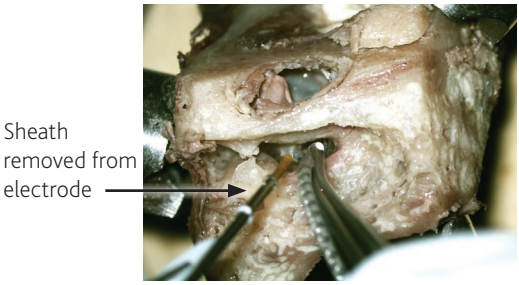



Figure 18: Electrode array fully inserted into cochlea and sheath removed

**Warning**

- Ensure the sheath is fully removed. The sheath needs to be completely removed from the electrode and **not** left in place after the procedure is complete.
- Keep the sheath in the sterile field in case it is needed for a second insertion attempt. See *Reloading the sheath* on page 56.

## Reloading the sheath

If electrode placement is suboptimal or the sheath is removed prematurely, the electrode may be reloaded for a second insertion attempt.

**Caution**

If the sheath is damaged, use a replacement Slim Modiolar Electrode Sheath.

**Warning**

Do not reload if the electrode is damaged – use a backup implant.

### Opening the replacement sheath

To open the Slim Modiolar Electrode Sheath tray:

#### 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 inner tray is not damaged.

   **Warning**

   If the sterile pack is damaged do not use the sheath.

#### Sterile field

3. Remove the inner tray, break the seal and remove the tray insert.
4. Lift the sheath from the tray.

   **Caution**

   To avoid damaging the sheath, do not hold it by the orange tip – hold the metal section or handle.

## Reloading the electrode into the sheath

1. Hold the sheath handle with forceps. Gently hold the electrode lead with AOS Forceps below the white alignment mark, as shown below.
2. Gently guide the electrode into the sheath tip, as shown below.
3. Slowly retract the electrode until it is completely inside the sheath and cannot be retracted further.

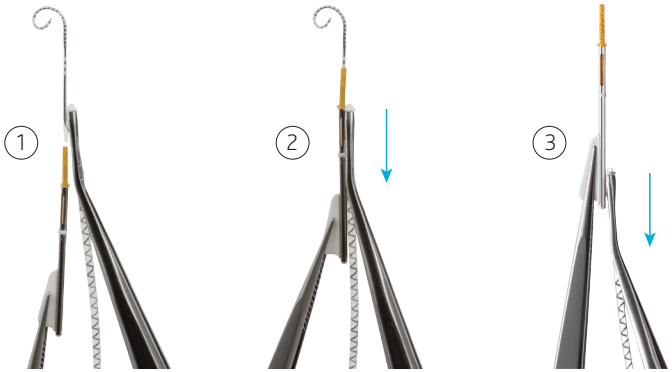



Figure 19: Guiding electrode into sheath and retracting electrode

**Caution**

Check that the electrode is fully contained within the sheath. If not, push the electrode entirely out and repeat from step 1.

4. To check that the electrode and sheath are functioning properly, push the electrode out until the white markers on the electrode array and sheath are aligned.
5. Slowly retract the electrode until it is completely inside the sheath and cannot be retracted further, ready for insertion into the cochlea.

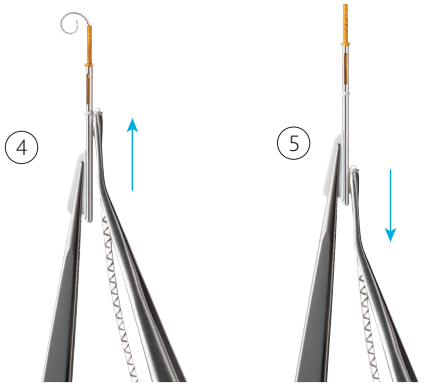



Figure 20: Sliding electrode through sheath and retracting

**Caution**

If the electrode is not fully inside the sheath or they do not function as illustrated above, use a backup implant.

# 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 in place continuously.

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.

   **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 see 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 sheath.

   **Warning**

   If using the Intraoperative Spacer, place the coil on top of the Intraoperative Spacer in the sterile sheath.
3. Place the external coil over the implant magnet.

   **Note**

   - The transmitting range of the cochlear implant is 1 mm to 10 mm. However, a maximum skin flap thickness of 6 mm to 9 mm is 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.

# Notes

# 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 three to four weeks after the operation. 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 identification card

Fill out the implant model number and ear details on the patient identification card. Give the card to the patient or their carer.

The patient or their carer should carry the patient identification 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. See *Cutting the intracochlear electrode lead* on page 66.
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.

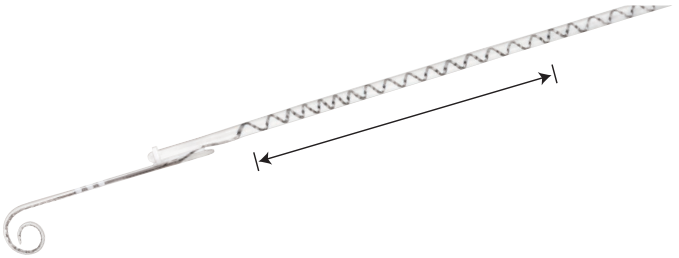


Figure 21: Where to cut electrode lead if required during explantation

# Reporting problems

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

# MRI safety information


The Cochlear Nucleus CI632 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.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.


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

## Removing the magnet

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

Before MRI, in some instances the implant magnet cassette must be removed in a sterile surgical environment. If single or multiple MRI examinations on the head are needed with the magnet removed, replace the implant magnet 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 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 is removed, the recipient must wear a retainer disc to hold their sound processor coil in place. Retainer discs are available from Cochlear.

## Replacement magnet and non-magnetic cassettes

**Warning**

To avoid implant damage during MRI 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.


Figure 22: Nucleus Replacement Magnet Cassette – P782485


Figure 23: Nucleus Non-Magnetic Cassette – P782484

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

## Removing the magnet before implantation

If an MRI 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 24: CI632 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

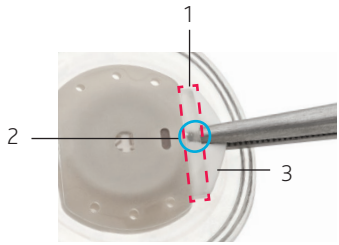



Figure 25: Forceps position on CI632 magnet cassette cover

**Caution**

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

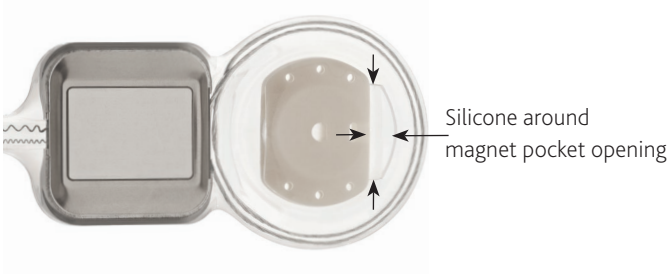



Figure 26: CI632 implant with magnet cassette removed

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 – see arrow in *Figure 27*.

**Caution**

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

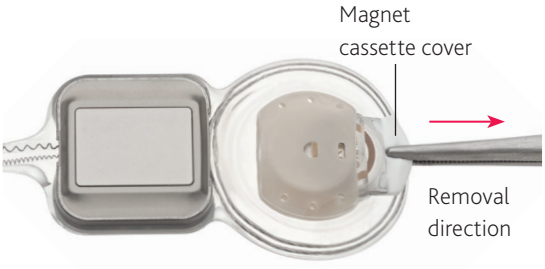



Figure 27: CI632 implant with magnet cassette partially removed

**Note**

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

Figure 28: Metal tab on magnet cassette


Figure 29: CI632 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.

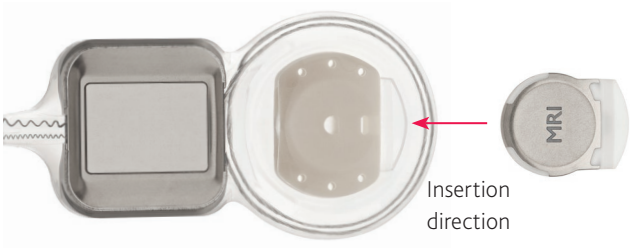



Figure 30: Non-magnetic cassette insertion direction

6. Ensure the non-magnetic cassette is fully inserted into the magnet pocket and the 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 or non-magnetic cassette after implantation* on page 74.

## Removing and replacing the magnet 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, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

Remove the magnet 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:

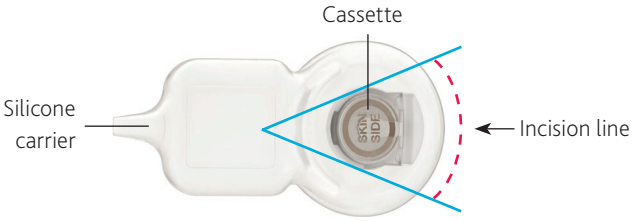



Figure 31: Marking the incision using the silicone carrier

2. Cut through any fibrous growth around the implant, exposing the distal end of the implant coil and the magnet cassette cover. Ensure there is good visibility and access to the magnet 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 magnet cassette cover.

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

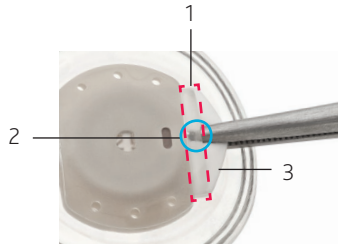



Figure 32: Forceps position on CI632 magnet cassette cover

5. Using constant traction, remove the magnet cassette from the magnet pocket. The removal direction is in the same plane as the implant coil, towards the distal end of the implant – see arrow in *Figure 33*.

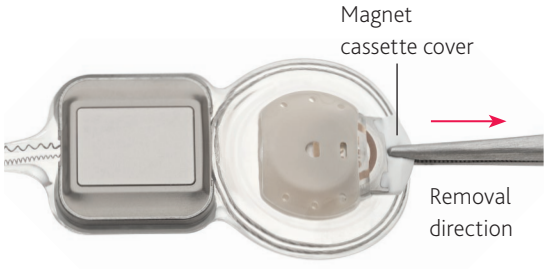



Figure 33: CI632 implant with magnet cassette partially removed

**Note**

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

Figure 34: Metal tab on magnet cassette


Figure 35: CI632 implant magnet cassette removal using metal tab

6. Dispose of the removed magnet cassette. It is 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 – see *Figure 36* 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).

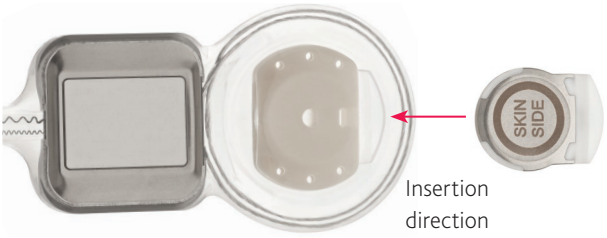



Figure 36: Replacement magnet cassette insertion direction

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 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.

# Notes

# 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 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

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

# CI632 implant specifications

| Intracochlear electrodes | |
|---|---|
| Number of electrodes | 22 electrodes |
| Distance between centres of electrode contacts | 0.6 mm nominal (when curled) |
| Cross-sectional dimensions of array | 0.475 mm x 0.5 mm at proximal end, tapering to 0.35 mm x 0.4 mm at distal end |
| Contact surface area | 0.15 $mm^2$ to 0.16 $mm^2$ |
| Active array length when straightened | 14 mm (distance between most basal and apical electrodes) |
| Lead length | 98 mm from receiver/stimulator to array tip when straightened |
| Markers for insertion depth | Three white, moulded silicone markers |

| Extracochlear electrodes |
|---|
| • Plate on receiver/stimulator<br>• 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<br>Coil: 31 mm diameter x 3.9mm 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 |
| Output signal on a 1 kΩ resistor | Amplitude 1750 µA, pulse width 400 µs |
| 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 to 10 mm (6 mm to 9 mm maximum skin flap thickness required for good magnet retention) |

| 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, bipolar 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<br><br>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.

## Symbols

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

| | |
|---|---|
|  | Fragile, handle with care |
|  | Do not use if package is damaged |
|  | Refer to instruction manual |
|  | 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 |

| | |
|---|---|
|  | Temperature limits |
|  | Keep dry |
| STERILE EO | Sterilised using ethylene oxide |
| Rx Only | Caution: US law restricts this device to sale by, or on the order of, a physician |
| REF | Catalogue number |
| SN | Serial number |
| LOT | Batch code |
| EC REP | Authorised representative in the European Community |
| CE | CE registration mark |
|  | MR Conditional |
| 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 |

Hear now. And always

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Cochlear®

# Cochlear™ Nucleus® Implants Magnetic Resonance Imaging (MRI) Guidelines

United States of America

Hear now. And always

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# About this guide

This guide applies to Cochlear™ Nucleus® implants. It is intended for:

- specialised health care professionals who prepare and perform MR scans
- physicians who refer a Cochlear Nucleus implant recipient for an MR scan
- Cochlear Nucleus implant recipients and/or their carers.

This guide provides information about the safe application of an MR scan on Cochlear Nucleus implant recipients.

MR scans performed under different conditions than those presented in this guide may result in severe patient injury or device malfunction.

Due to the risks associated with using MRI with an implanted medical device, it is important to read, understand, and comply with these instructions to prevent potential harm to the patient and/or device malfunction.

This guide should be read in conjunction with the relevant documents that accompany a Cochlear Nucleus implant, such as the Physician's Guide and Patient Information, or the Surgeon's Guide, Physician's Package Insert and Important Information Booklet. For more information, visit www.cochlear.com/warnings or contact Cochlear on +1 866 210 9217.

# 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

# Notes

# MRI safety information

In order to determine if a patient may receive an MR scan, you must first identify the patient's Cochlear Nucleus implant model.

After you have identified the implant model, see ***Implant model identification and related MRI safety information*** on page 9 to locate the MRI safety information for that specific implant model.


All external components of the Cochlear implant system (e.g. sound processors, remote assistants 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.

## Identifying the Cochlear Nucleus implant

The implant model can be found on the patient's Cochlear patient identification card.

If the patient does not have their patient identification card with them, the implant type and model can be identified without surgical intervention. See ***X-ray information for identification of Cochlear Nucleus implants*** on page 8 and ***Implant model identification and related MRI safety information*** on page 9.

# X-ray information for identification of Cochlear Nucleus implants

Cochlear Nucleus implants are made of metal and implanted under the skin behind the ear.

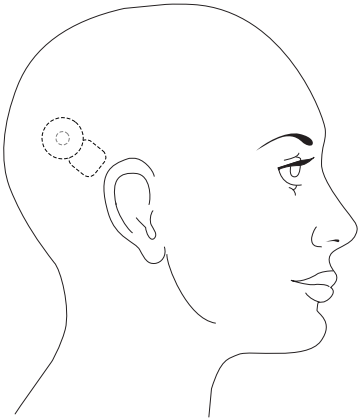


Figure 1: Location behind the ear for Cochlear Nucleus implants

## X-ray guidelines

Lateral X-ray at 70 kV/ 3 mAs provides sufficient contrast to identify the implant.

A modified Stenver's view is not recommended for implant identification as implants may appear oblique.

Imaging should include an unobstructed view of antenna coils and implant bodies.

# Implant model identification and related MRI safety information

Cochlear Nucleus implants that can be identified by the radiopaque characters printed on them are:

- CI24RE Series – CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS) and CI24RE (ST)
- Nucleus 24 – CI24R (CA), CI24R (CS), CI24R (ST), CI24M, CI11+11+2M and ABI24M
- Nucleus 22 – CI22M

There are three sets of radiopaque characters printed on each implant.

The second (middle) radiopaque character set identifies the implant model.

Cochlear Nucleus CI600 Series implants - CI612, CI622, CI624 and CI632 and CI500 Series implants – CI512, CI522 and CI532 – do not have radiopaque characters. Using an X-ray, CI500 Series and CI600 Series implants can be identified by the implant shape and electronic assembly layout. If further implant details are required, contact your Cochlear representative who will provide instructions on how to determine the following:

- Manufacturer
- Model
- Year of manufacture

The electronic assembly layout is identical for Cochlear CI600 and CI500 Series implants. The unique identifier for CI600 Series implants is the magnet shape and three holes next to the magnet, as illustrated below.

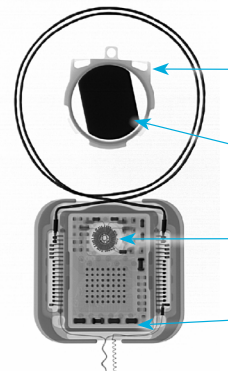
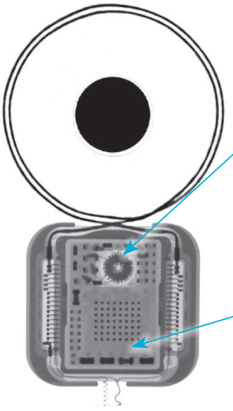
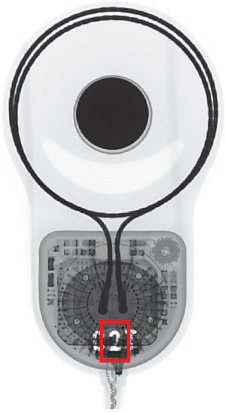
<table>
<tr><th>Cochlear Nucleus implant model</th><th>Electronic assembly</th><th>Unique identifier</th><th>MRI safety information</th></tr>
<tr><td>CI612</td><td rowspan="4">  <br>Figure 2: CI600 Series implant X-ray</td><td rowspan="4">Three holes adjacent to magnet<br>Magnet shape<br>Round shape at coil exit end of electronic assembly layout.<br>Four rectangular shapes at electrode exit end.</td><td>Page 13</td></tr>
<tr><td>CI622</td><td>Page 17</td></tr>
<tr><td>CI624</td><td>Page 21</td></tr>
<tr><td>CI632</td><td>Page 25</td></tr>
<tr><td>CI512</td><td rowspan="3">  <br>Figure 3: CI500 Series implant X-ray</td><td rowspan="3">Round shape at coil exit end of electronic assembly layout.<br>Four rectangular shapes at electrode exit end.</td><td>Page 29</td></tr>
<tr><td>CI522</td><td>Page 33</td></tr>
<tr><td>CI532</td><td>Page 37</td></tr>
</table>

Table 1: Cochlear Nucleus implant models identified by their shape and electronic assembly.

| Cochlear Nucleus implant model | Location of second (middle) radiopaque character set | Radiopaque characters | MRI safety information |
|---|---|---|---|
| CI422 |  | 13 | Page 41 |
| CI24REH (Hybrid L24) | | 6 | Page 45 |
| CI24RE (CA) | | 5 | Page 49 |
| CI24RE (CS) | | 7 | Page 49 |
| CI24RE (ST) | | 4 | Page 53 |
| CI24R (CA) | | 2 | Page 57 |
| CI24R (CS) | | C | Page 58 |
| CI24R (ST) | | H | Page 59 |
| CI24M |  | T | Page 60 |
| CI 11+11+2M | | P | Page 61 |
| ABI24M | | G | Page 62 |

| Cochlear Nucleus implant model | Location of second (middle) radiopaque character set | Radiopaque characters | MRI safety information |
|---|---|---|---|
| CI22M with removable magnet |  | L or J | Page 63 |
| CI22M without removable magnet | | Z | |

Table 2: Cochlear Nucleus implant models identified by second (middle) radiopaque character set and related MRI safety information

# MRI safety information for CI612 cochlear implants

Non-clinical testing has demonstrated that CI612 implants are MR Conditional. A patient with one or two of these devices can be safely scanned in an MR system meeting the following conditions.

**Note**

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field

## CI612 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI612 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI612 cochlear implant is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

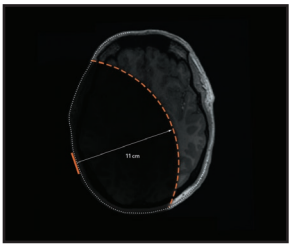
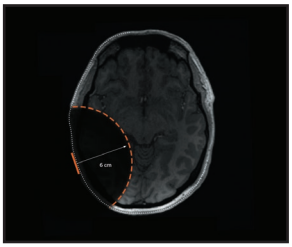
| 1.5 T with magnet cassette | 1.5 T with non-magnetic cassette |
|---|---|
|   |   |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI612 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 3: Largest image artefact for CI612 cochlear implants at 1.5 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

## CI612 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI612 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI612 cochlear implant is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

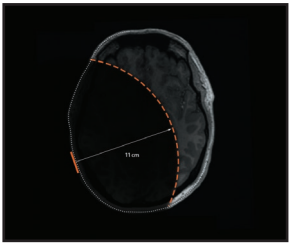
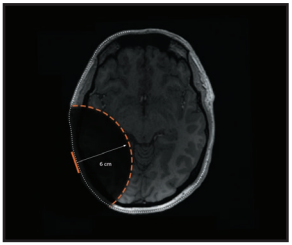
| 3 T with magnet cassette | 3 T with non-magnetic cassette |
|---|---|
|  |  |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI612 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 4: Largest image artefact for CI612 cochlear implants at 3 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

# MRI safety information for CI622 cochlear implants

Non-clinical testing has demonstrated that CI622 implants are MR Conditional. A patient with one or two of these devices can be safely scanned in an MR system meeting the following conditions.

**Note**

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field

## CI622 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI622 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI622 cochlear implant is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

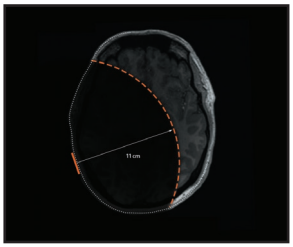
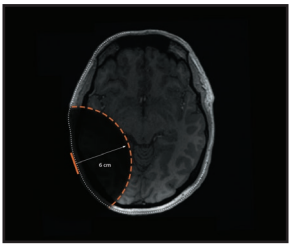
| 1.5 T with magnet cassette | 1.5 T with non-magnetic cassette |
|---|---|
|   |   |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI622 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 5: Largest image artefact for CI622 cochlear implants at 1.5 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

## CI622 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI622 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI622 cochlear implant is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

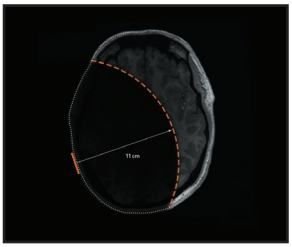
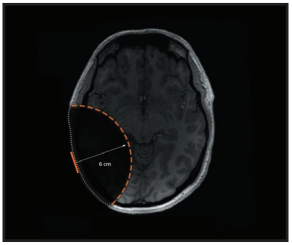
| 3 T with magnet cassette | 3 T with non-magnetic cassette |
|---|---|
|  |  |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI622 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 6: Largest image artefact for CI622 cochlear implants at 3 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

# MRI safety information for CI624 cochlear implants

Non-clinical testing has demonstrated that CI624 implants are MR Conditional. A patient with one or two of these devices can be safely scanned in an MR system meeting the following conditions.

**Note**

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field

## CI624 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
  - It is safe to use local cylindrical RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI624 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI624 cochlear implant is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

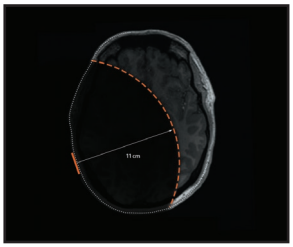
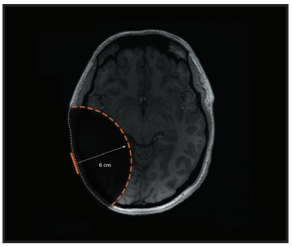
| 1.5 T with magnet cassette | 1.5 T with non-magnetic cassette |
|---|---|
|   |   |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI624 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI624 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 7: Largest image artefact for CI624 cochlear implants at 1.5 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

## CI624 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
  - It is safe to use local cylindrical RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI624 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI624 cochlear implant is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

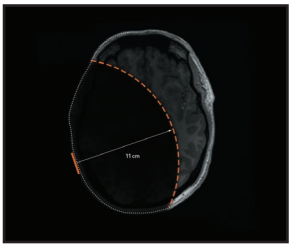
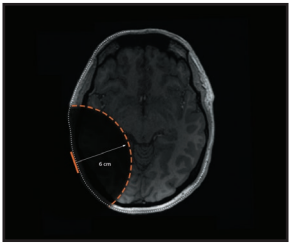
| 3 T with magnet cassette | 3 T with non-magnetic cassette |
|---|---|
|  |  |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI624 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI624 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 8: Largest image artefact for CI624 cochlear implants at 3 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

# MRI safety information for CI632 cochlear implants

Non-clinical testing has demonstrated that CI632 implants are MR Conditional. A patient with one or two of these devices can be safely scanned in an MR system meeting the following conditions.

**Note**

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field

## CI632 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI632 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI632 cochlear implant is as follows.

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

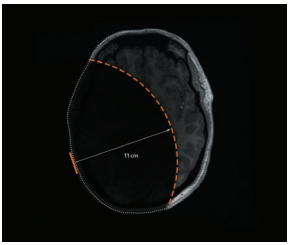
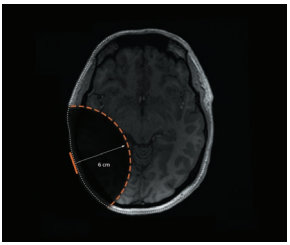
| 1.5 T with magnet cassette | 1.5 T with non-magnetic cassette |
|---|---|
|  |  |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI632 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 9: Largest image artefact for CI632 cochlear implants at 1.5 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

## CI632 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
  - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
  - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI632 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing[1], the image artefact caused by the CI632 cochlear implant is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

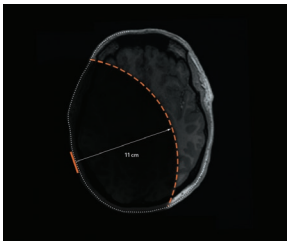
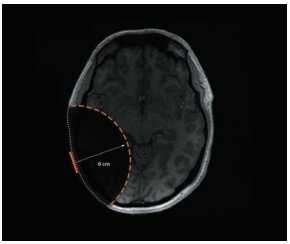
| 3 T with magnet cassette | 3 T with non-magnetic cassette |
|---|---|
|   |   |
| The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan. | The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI632 cochlear implant when using a spin echo pulse sequence scan. |
| For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants. | |

Table 10: Largest image artefact for CI632 cochlear implants at 3 T scans

1 Image artefact testing undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case results provided

# MRI safety information for CI512 cochlear implants

Non-clinical testing has demonstrated that CI512 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

## CI512 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI512 cochlear implant with Contour Advance® electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

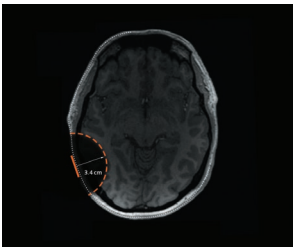
| 1.5 T magnet removed |
| --- |
|   |
| 3.4 cm (1.3 in.) |

Table 11: Largest image artefact for CI512 cochlear implants at 1.5 T scans

## CI512 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI512 cochlear implant with Contour Advance® electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.7 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

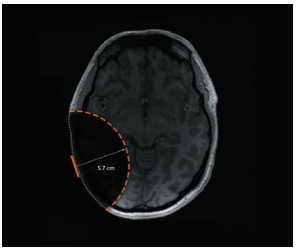
| 3 T magnet removed |
| --- |
|  |
| 5.7 cm (2.2 in.) |

Table 12: Largest image artefact for CI512 cochlear implants at 3 T scans

# MRI safety information for CI522 cochlear implants

Non-clinical testing has demonstrated that CI522 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

## CI522 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI522 cochlear implant with Slim Straight electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.

Under the scan conditions defined above, the CI522 cochlear implant is expected to produce a maximum temperature rise of less than 3.8 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI522 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

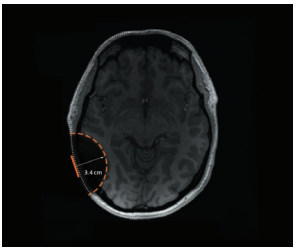
| 1.5 T magnet removed |
| --- |
|   |
| 3.4 cm (1.3 in.) |

Table 13: Largest image artefact for CI522 cochlear implants at 1.5 T scans

## CI522 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI522 cochlear implant with Slim Straight electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI522 cochlear implant is expected to produce a maximum temperature rise of less than 4.9 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI522 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

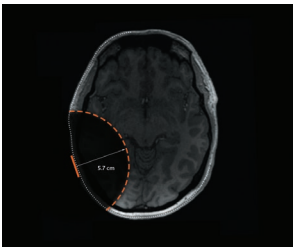
| 3 T magnet removed |
| --- |
|  |
| 5.7 cm (2.2 in.) |

Table 14: Largest image artefact for CI522 cochlear implants at 3 T scans

# MRI safety information for CI532 cochlear implants

Non-clinical testing has demonstrated that CI532 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

## CI532 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI532 cochlear implant with Slim Modiolar electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.

Under the scan conditions defined above, the CI532 cochlear implant is expected to produce a maximum temperature rise of less than 4.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI532 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

## Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

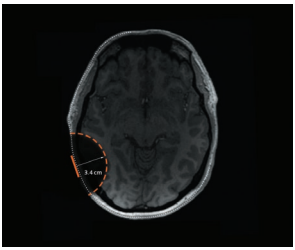
| 1.5 T magnet removed |
| --- |
|   |
| 3.4 cm (1.3 in.) |

Table 15: Largest image artefact for CI532 cochlear implants at 1.5 T scans

## CI532 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI532 cochlear implant with Slim Modiolar electrode - Physician's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI532 cochlear implant is expected to produce a maximum temperature rise of less than 5.4 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI532 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

## Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

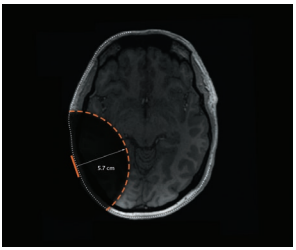
| 3 T magnet removed |
| --- |
|  |
| 5.7 cm (2.2 in.) |

Table 16: Largest image artefact for CI532 cochlear implants at 3 T scans

# MRI safety information for CI422 cochlear implants

Non-clinical testing has demonstrated that CI422 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

## CI422 cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI422 cochlear implant with straight electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.

Under the scan conditions defined above, the CI422 cochlear implant is expected to produce a maximum temperature rise of less than 4.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI422 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

## Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

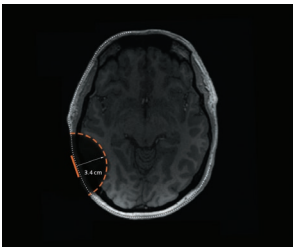
| 1.5 T magnet removed |
| --- |
|   |
| 3.4 cm (1.3 in.) |

Table 17: Largest image artefact for CI422 cochlear implants at 1.5 T scans

## CI422 cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® CI422 cochlear implant with straight electrode - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI422 cochlear implant is expected to produce a maximum temperature rise of less than 2.2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI422 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

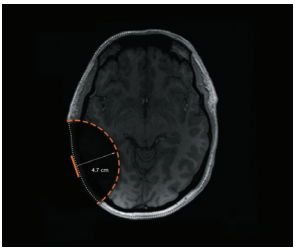
| 3 T magnet removed |
| --- |
|  |
| 4.7 cm (1.9 in.) |

Table 18: Largest image artefact for CI422 cochlear implants at 3 T scans

# MRI safety information for CI24REH (Hybrid L24) cochlear implants

Non-clinical testing has demonstrated that CI24REH (Hybrid L24) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

## CI24REH (Hybrid L24) cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Hybrid™ L24 cochlear implant CI24REH - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.

Under the scan conditions defined above, the CI24REH (Hybrid L24) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24REH (Hybrid L24) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

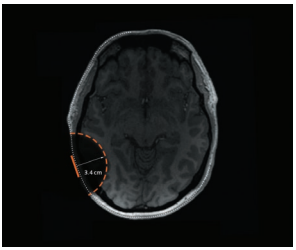
| 1.5 T magnet removed |
| --- |
|   |
| 3.4 cm (1.3 in.) |

Table 19: Largest image artefact for CI24REH (Hybrid L24) cochlear implants at 1.5 T scans

## CI24REH (Hybrid L24) cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Hybrid™ L24 cochlear implant CI24REH - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24REH (Hybrid L24) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24REH (Hybrid L24) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

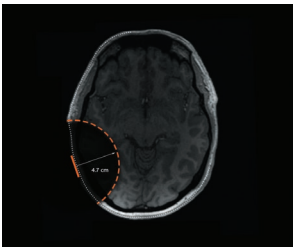
| 3 T magnet removed |
| --- |
|  |
| 4.7 cm (1.9 in.) |

Table 20: Largest image artefact for CI24REH (Hybrid L24) cochlear implants at 3 T scans

# MRI safety information for CI24RE (CA) cochlear implants

## Note

This MRI safety information also applies to CI24RE (CS) cochlear implants.

Non-clinical testing has demonstrated that CI24RE (CA) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

## CI24RE (CA) cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Contour Advance® electrode CI24RE (CA) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.

Under the scan conditions defined above, the CI24RE (CA) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

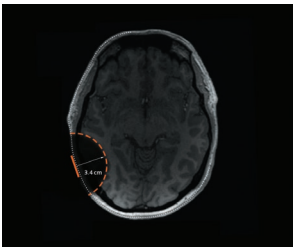
| 1.5 T magnet removed |
| --- |
|   |
| 3.4 cm (1.3 in.) |

Table 21: Largest image artefact for CI24RE (CA) cochlear implants at 1.5 T scans

## CI24RE (CA) cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Contour Advance® electrode CI24RE (CA) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24RE (CA) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

## Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

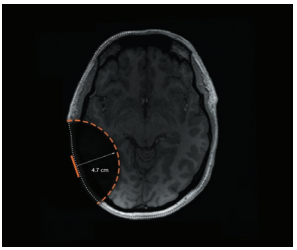
| 3 T magnet removed |
| --- |
|  |
| 4.7 cm (1.9 in.) |

Table 22: Largest image artefact for CI24RE (CA) cochlear implants at 3 T scans

# MRI safety information for CI24RE (ST) cochlear implants

Non-clinical testing has demonstrated that CI24RE (ST) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

## CI24RE (ST) cochlear implants and 1.5 T scans

- **Surgically remove the implant magnet before MR scans at 1.5 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Straight electrode CI24RE (ST) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg is required.

Under the scan conditions defined above, the CI24RE (ST) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

### Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

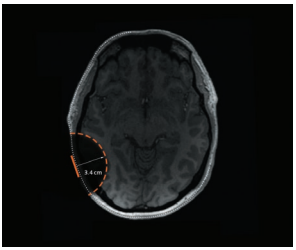
| 1.5 T magnet removed |
| --- |
|   |
| 3.4 cm (1.3 in.) |

Table 23: Largest image artefact for CI24RE (ST) cochlear implants at 1.5 T scans

## CI24RE (ST) cochlear implants and 3 T scans

- **Surgically remove the implant magnet before MR scans at 3 T.**

  Please refer to *Removing the magnet* in the *Nucleus® Freedom® implant with Straight electrode CI24RE (ST) - Surgeon's Guide* for more information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24RE (ST) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

## Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

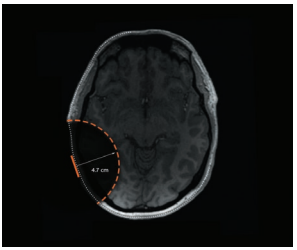
| 3 T magnet removed |
| --- |
|  |
| 4.7 cm (1.9 in.) |

Table 24: Largest image artefact for CI24RE (ST) cochlear implants at 3 T scans

# MRI safety information for CI24R (CA) cochlear implants

## Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (CA) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

# MRI safety information for CI24R (CS) cochlear implants

## ⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (CS) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

# MRI safety information for CI24R (ST) cochlear implants

## ⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (ST) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

# MRI safety information for CI24M cochlear implants

## ⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24M cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

# MRI safety information for CI 11+11+2M cochlear implants

## Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI 11+11+2M cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

# MRI safety information for ABI24M auditory brainstem implants

## ⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow patients with an ABI24M auditory brainstem implant to be in the room where an MRI scanner is located except under the following special circumstances.

The ABI24M auditory brainstem implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher. If the ABI24M auditory brainstem implant magnet is in place, it must be removed surgically before the patient undergoes an MRI procedure.

The patient must take off the speech processor and headset before entering a room where an MRI scanner is located.

If the implant magnet is still in place, tissue damage may occur if the recipient is exposed to MRI. Once the magnet is surgically removed, the metal in the ABI24M auditory brainstem implant will affect the quality of the MRI. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, resulting in loss of diagnostic information in the vicinity of the implant.

ABI24M auditory brainstem implants have removable magnets. Once the magnet has been removed, MRI can be performed. The headset can be held in place on the recipient's head by a stick-on retainer disk.

If you require additional information about removal of the magnet, please contact Cochlear.

# MRI safety information for CI22M cochlear implants

## ⚠ Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI22M cochlear implant with removable magnet has specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

For patients with a CI22M cochlear implant without a removable magnet, MRI is contraindicated.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

# Preparation prior to an MRI examination

## Cooperation between specialists

Preparing for and conducting an MRI examination for implant recipients requires cooperation between a specialist for the device and/or Cochlear Nucleus implant physician, referring physician and radiologist / MR technologist.

- Cochlear Nucleus implant device specialist – Knows the implant type and where to find the correct MR parameters for the implant.
- Referring physician – Knows the location of the MR scan and diagnostic information required, and makes a decision on whether the implant magnet needs to be removed for the MRI examination.
- Cochlear Nucleus implant physician – if requested by the referring physician, surgically removes the implant magnet and replaces it with a new sterile replacement implant magnet (after the MR scan).
- Radiologist / MR technologist – Sets up the MR scan using the correct MR parameters and counsels the implant recipient during the MRI examination.

## Considerations for implant magnet removal

For Cochlear implants other than CI600 Series implants, the implant magnet needs to be removed prior to an MRI examination. Close coordination is required between the specialists to perform the implant magnet removal, MR scan, and subsequent implant magnet replacement.

For CI600 Series implant recipients, if single or multiple MRI examinations on the head are needed with the magnet removed, the implant magnet must be replaced (in a sterile surgical environment) with a non-magnetic cassette.

Please refer to ***Removing the magnet*** under ***MRI safety information*** in the implant ***Surgeon's Guide*** or ***Physician's Guide*** for more information on surgically removing the implant magnet.

### Warning

To prevent infection, do not leave the magnet pocket empty for CI600 implants. When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.

For all other implant recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the non-magnetic plug prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.

### Note

While the magnet is removed, the recipient must wear a retainer disc to hold their external transmitter coil in place. Retainer discs are available from Cochlear.

When there is no further need for MRI examinations, the non-magnetic cassette / non-magnetic plug is removed and replaced by a new sterile replacement implant magnet.

The non-magnetic cassette / non-magnetic plug and replacement implant magnet cassette and implant magnet are supplied separately in sterile packs. Both are single-use items.

# Considerations for conducting an MRI examination

These guidelines are specific to Cochlear Nucleus implants and supplement other MRI examination considerations specified by the MRI machine manufacturer or protocols at the MRI facility.

## Prerequisites

The following additional conditions must be met:

- The implant model has been identified.
- The implant magnet has been surgically removed if the referring physician has prescribed that the MR scan be performed with the implant magnet removed.

## Patient positioning

The patient should be positioned prior to entering the MRI machine. Prior to performing the MR scan, the patient should be placed in the supine position (lying flat on back, face upward), with their head aligned with the bore axis of the MRI machine.

The patient should be advised to lie as still as possible and to not move their head during the MR scan.

**⚠ Caution**

Failure to position the patient correctly prior to the MR scan may result in increased torque on the implant and cause pain. It may also result in implant demagnetisation. If the patient moves their head during the MR scan, this may also result in increased torque on the implant or possible magnet demagnetisation.

## Perform the MR scan

The MR scan must be performed using the MRI safety information identified for the patient's implant model. See *Identifying the Cochlear Nucleus implant* on page 7 to find the location of the MRI safety information for the patient's implant model.

## Performing an MR Scan on other body locations

When an implant recipient requires an MRI on a location of their body away from the implant site, you must still follow the MRI safety information for the recipient's implant model. See *Implant model identification and related MRI safety information* on page 9 to find the location of the MRI safety information for the patient's implant model.

# Considerations for referring physicians

If you are a physician referring a Cochlear Nucleus implant recipient for an MR scan, it is essential that you consider the following:

- Understand and inform the patient of the risks associated with MRI. See *Risks associated with MRI and Cochlear Nucleus implants* on page 70.

  Understand the conditions for an MR scan and ensure that there is a clear indication for the MRI examination. See *Implant model identification and related MRI safety information*on page 9 to find the location of the MRI safety information for the patient's implant model.
- Identify if the patient has any other medical device implants, active or abandoned. If another implanted device is present, verify MRI compatibility before conducting an MRI examination. If MRI safety information for the implanted devices are not followed, the potential risks include movement or damage to the device, weakening of the implant magnet and uncomfortable sensation or skin/tissue trauma for the patient. Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning.
- The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant MRI Safety information for your impant.
- For MR scans on a body location away from the implant site, MRI safety information for the recipient's implant model must be followed. See *Performing an MR Scan on other body locations* on page 67.

- For MR Scans at 1.5 T or 3 T, identify if the implant magnet needs to be removed.


Figure 4: CI600 Series implant with removable magnet

Consider the following:

  - If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed.
  - Timing of the implant surgery and MRI exposure.
  - Age and general health of the implant recipient and time to recover from the implant magnet surgery or potential trauma.
  - Existing or potential for tissue scarring in the location of the implant magnet.
- If the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for the magnet to be removed before the MR scan.

# Risks associated with MRI and Cochlear Nucleus implants

The potential risks of performing MRI examinations on patients with Cochlear Nucleus implants include:

- Device movement

  The implant magnet or device may move out of position during an MRI examination due to vibration, force or torque causing skin/ tissue trauma.

- Damage to the device

  MRI exposure beyond the values contained in these guidelines may cause damage to the device.

- Weakening of implant magnet
  - Scanning at static magnetic field strengths at values other than those contained in these guidelines may lead to a weakening of the implant magnet.
  - Incorrect patient positioning prior to the MR scan or head movement during the scan may result in implant demagnetisation.

- Uncomfortable sensation

  MRI exposure beyond the values contained in these guidelines may result in the patient perceiving sound or noise and / or pain.

- Implant heating

  Use the recommended SAR values contained in these guidelines to ensure the implant does not heat beyond safe levels.

- Image artefact

  The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information.

  If inspecting near the implant, removal of the implant magnet should be considered as MR image quality may be compromised with it in place.

# Labelling symbols

The following symbols may appear on the product, the components and/or the packaging.

| | |
|---|---|
|  | Refer to instruction manual |
|  | Specific warnings or precautions associated with the device, which are not otherwise found on the label |
|  | Manufacturer |
|  | Date of manufacture |
|  | Catalogue number |
|  | Authorised representative in the European Community |
|  | Keep dry |
|  | Do not re-use |
|  | Do not use if package is damaged |
| Rx Only | By prescription |
|  | MR Conditional |

# Notes

Hear now. And always

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