CI532

Cochlear™ Nucleus® CI532 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® 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 anaesthetic-related adverse events, a paediatric anaesthesiologist should be present during surgery for infants implanted under 12 months of age.
- 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 2.5 cm (1 in) from the edge of the implant, with or without external sound processor magnet coupled to it, in any direction is less than 300 Gauss.

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 78.

Cautions

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

Note

- **Facial nerve monitor** use is advised, particularly for cases where the facial nerve may be at greater risk such as congenital temporal bone anomalies and revision surgeries.
- For device electromagnetic compatibility (EMC) information, see *Electromagnetic Compatibility (EMC)* on page 89.

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 to the auditory nerve. Both adults and paediatrics are candidates for cochlear implantation. There is an indication for adult and paediatric candidates with bilateral sensorineural hearing loss and an indication for adult and paediatric candidates with unilateral hearing loss or single sided deafness.

Bilateral sensorineural hearing loss

Adults

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

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

Children

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

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

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

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

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

Adults and children

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

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

Contraindications

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

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

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

- Duration of profound sensorineural hearing loss greater than ten years

Note

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

Adverse effects

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

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

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

Meningitis

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

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

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

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

Loss of residual hearing

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

Results of clinical studies

Summary of safety data

The following information summarises adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant system. Safety data apply to all patients receiving a cochlear implant and are not specific to individuals with bilateral sensorineural hearing loss or single sided deafness/unilateral hearing loss.

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

Medical or 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

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

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

Medical/Surgical complications[1]

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.

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

Device-related complications

No device failures or other serious device malfunctions were observed during the first study. Thirteen 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.

Additional summary of safety for children

Cochlear performed a prospectively-designed, retrospective analysis from its own registry data to establish a reasonable assurance of safety of implantation with the Cochlear Nucleus 24 cochlear implant system for paediatric patients aged 9 months to 12 months. The retrospective review of 84 children that were between 9 months and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for this analysis. Twenty four patients experienced 28 medical or 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. Six patients experienced minor postoperative complications, 4 of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage perioperatively. These were repaired during the cochlear implant surgery, and one patient required a revision surgery with reimplantation. Two patients experienced postoperative 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 postoperative meningitis. Overall, the above adverse events are typical surgical, procedure or device events observed in children implanted in relatively young age.

Additionally, in February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess safety of implantation with a Cochlear Nucleus cochlear implant in infants aged between 9 months and 12 months. A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old. Safety studies that included children implanted at less than 12 months old covered a broad range of topics from surgical complications including anaesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and postoperative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

Summary of effectiveness data

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

Adults

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

Cochlear analysed retrospective data to demonstrate the effectiveness of cochlear implantation in adults with SSD. For the data analysed, the ear to be implanted had a profound sensorineural hearing loss (PTA of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) ≥ 70 dB HL, and an aided CNC word score of ≤ 10%. The contralateral ear had normal or near normal hearing (PTA 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) ≤ 30 dB HL.

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

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

Effectiveness testing included speech recognition testing using:

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

Patient reported outcomes were evaluated with the Speech, Spatial, and Qualities (SSQ) Questionnaire and the Iowa Tinnitus Handicap Questionnaire. Audiometric thresholds were also obtained for each ear.

Description of Tests

Hearing in Noise Test (HINT)

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

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

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

Localisation Testing

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

Speech, Spatial, and Qualities (SSQ) Questionnaire

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

Speech hearing scale – This includes hearing speech in quiet and in noise, in one-on-one conversation and in groups or meetings.

Spatial hearing scale – This includes hearing where sounds are coming from, distance, movement, and ability to segregate sounds.

Qualities of sound scale – This includes ease of listening, naturalness, clarity, identification of different speakers, musical pieces and instruments, as well as everyday sounds.

Iowa Tinnitus Handicap Questionnaire

The Iowa Tinnitus Handicap Questionnaire was used to assess tinnitus. Tinnitus was assessed before and after the cochlear implant was turned on. There are 27 questions that fall into 3 factors:

Factor 1 examines social, physical and emotional wellbeing.

Factor 2 examines hearing abilities.

Factor 3 examines an individual's view of tinnitus.

Speech recognition results

The primary and secondary effectiveness objectives and endpoints of the study are shown in *Table 1*.

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

Table 1: Summary of study effectiveness objectives and endpoints

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

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

As shown in *Table 2*, when speech was presented from the front speaker and noise to the normal hearing ear ($S0N_{NH}$), there was a postactivation improvement in the bimodal listening condition (cochlear implant + normal hearing) compared to the best preoperative listening condition. On average, participants experienced an improvement of 2.8 dB, (95% confidence interval, -4.1 to -1.4). A negative value connotes benefit with a cochlear implant for this test.

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

Table 2: Co-primary endpoint 1:
Speech understanding in noise preoperative to postactivation ($S0N_{NH}$) (N=23)

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

Table 3 summarises the results for 38 participants, who had data available postactivation comparing performance in the bimodal listening condition (cochlear implant + normal hearing) compared to performance in normal hearing (NH) ear alone condition (cochlear implant off). The postactivation interval ranged from 3 months to 86 months with a mean of 20 months. Improvement was found in the bimodal condition (cochlear implant + normal hearing) compared to normal hearing alone (cochlear implant off) for speech understanding in noise ($S0N_{NH}$). Participants on average experience a 1.5 dB improvement (95% confidence interval, -2.1 to -0.9) in the bimodal condition compared to listening with the normal hearing ear alone.
A negative value connotes benefit with a cochlear implant for this test.

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

Table 3: Statistical summary for co-primary effectiveness endpoint 2: Bimodal (CI + NH) performance relative to NH ear alone (CI off) performance postoperatively (N=38)

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

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

In examining individual subject performance, it was found in the preoperative best bilateral listening (hearing aid + normal hearing/ normal alone) to postactivation (cochlear implant + hearing aid) comparison that:

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

When comparing performance postactivation in the bimodal condition (cochlear implant + normal hearing) (cochlear implant on) compared to normal hearing ear alone (cochlear implant off), it was found that:

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

In the clinical study, it was found that 8/38 (21%) experienced a decrease in speech understanding in noise when speech was presented from the front speaker and noise was directed to the cochlear implant side, suggesting potential interference of the overlapping electric and acoustic signal in bilateral hearing. Additionally, a few published studies (Speck et al., 2020, Deep et al., 2021, and Zeitler et al.,2019) reported that there was a low incidence of cochlear implant nonuse presumably because of lack of perceived benefit of the cochlear implant. Given these results, it is reasonable to conclude that a small number of recipients experience perceptual interference of overlapping acoustic and electric bilateral hearing.

Cochlear performed subgroup analyses to examine the consistency of co-primary effectiveness endpoints. The following subgroups were examined: gender, median age at implant, median duration of hearing loss at baseline, etiology of hearing loss, evaluation interval, median baseline/preoperative speech in noise score, median baseline CI off speech in noise score, and preoperative pure tone average (PTA).

Results indicated that the only baseline characteristics that affected the primary endpoint 1 were 1) duration of hearing loss, 2) etiology of hearing loss and 3) pre-operative speech in noise score. The mean score for participants below or equal to the median duration of hearing loss of 2 years was significantly poorer than that for duration of hearing loss above 2 years. It was found that those participants with an etiology of sudden sensorineural hearing loss performed significantly better than those with Meniere's disease or the other group. This result should be interpreted with caution as the majority of etiologies were classified as other. It was found that those participants who had poorer preoperative speech in noise scores demonstrated significantly greater improvement.

For coprimary effectiveness endpoint 2, the only baseline characteristic that affected the endpoint was baseline speech in noise for the spatial configuration $S0N_{NH}$ obtained in the CI off condition (NH alone). Participants with poorer speech understanding in noise (>1.2 dB) in the CI off condition demonstrated significantly more improvement in the bimodal listening condition (CI + NH).

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

Secondary effectiveness endpoint

Twenty four participants had localisation data available for analysis. *Table 4* summarises the results on the localisation test showing the root mean square (RMS) error. The RMS error was significantly improved by 18.8 degrees, in the bimodal condition (cochlear implant + normal hearing) compared to the normal hearing (cochlear implant off) ear alone.

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

Table 4: Localisation outcomes (N=24)

Patient reported outcomes

There were 14 participants who completed the SSQ preoperatively and 10 participants who completed it at 6 months postactivation. As shown in *Table 5*, there was a significant mean improvement on each subscale, with the biggest difference found on the Spatial Hearing subscale. Preoperative to postactivation mean differences were significant based on paired t-tests.

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

Table 5: Preoperative to 6 month postactivation statistical outcomes for the SSQ49

Iowa Tinnitus Handicap Questionnaire

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

Children

Effectiveness of the Cochlear Nucleus 24 cochlear implant system in older children (5 years and above) was assessed by comparing the speech perception abilities of 23 prelinguistically and postlinguistically deafened participants 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 6 months of device use. Postoperatively, the Cochlear Nucleus 24 cochlear implant 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 5 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 6 months of experience with the Cochlear Nucleus 24 cochlear implant system, on all 11 measures of speech perception administered to children 5 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 6 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 6 months of experience with the Cochlear Nucleus 24 cochlear implant system:

- 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 Cochlear Nucleus 24 cochlear implant 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 6 months of implant use. Postoperatively, the Cochlear Nucleus 24 cochlear implant 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 6 months of experience with the Cochlear Nucleus 24 cochlear implant system:

- 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.

Additional summary for effectiveness for younger children (ages 9 months to 12 months)

Additionally, in February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess effectiveness of implantation with a Cochlear Nucleus cochlear implant in infants aged between 9 months and 12 months. A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old. Effectiveness outcomes from the literature data support that implantation before 12 months of age supports paediatric cochlear implant recipients' improved speech and language development.

Device description

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

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

Implanted component

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

External components

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

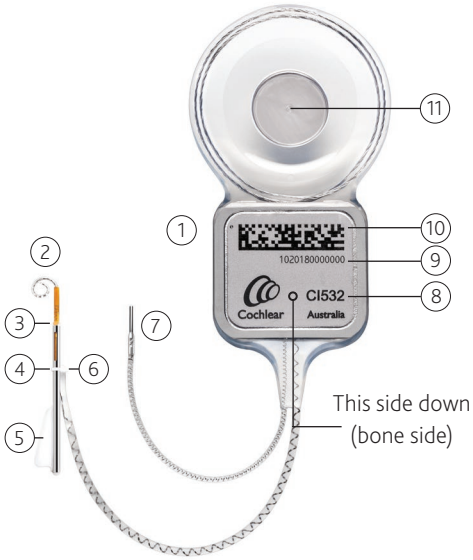
The system is programmed by a Cochlear proprietary programming software.

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

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)

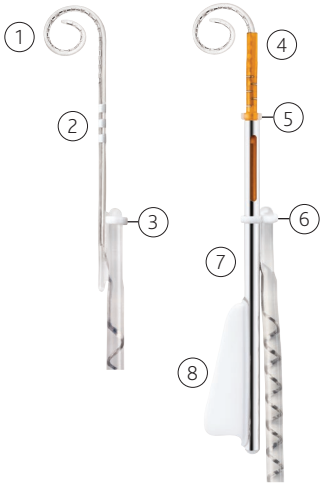
Figure 1: CI532 cochlear implant with Slim Modiolar electrode (bone side)

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 and accessories

Instruments and accessories in this section are appropriate for use with Cochlear Nucleus CI500 Series implants.

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

Instruments	Product code	CI500 Series Instrument Kit	CI500 Series Instrument Upgrade Kit
AOS™ Forceps for the Contour Advance® Electrode	Z60770	✓	✓
BTE Template	Z33011	✓	–
CI500 Series Recess Gauge	Z139274	✓	✓
CI500 Series Implant Template	Z139273	✓	✓
Contour® Electrode Claw	Z33021	✓	–
Electrode Claw (Straight)	Z30090	–	–
Contour Advance® Depth Gauge	Z179994	–	–
Depth Gauge (Straight)	Z60006	–	–
CI500 Series Sterile Silicone Implant Template*	S211296	–	–
CI500 Series Non-Sterile Silicone Implant Template	Z179609	–	–
Spacer for Intraoperative Testing	Z33012	–	–
Cochleostomy Sizing Tool*	Z341279	–	–
Slim Modiolar Electrode Sheath	P1291522	–	–
Accessories			
CI500 Series Non-Magnetic Plug	Z146624	–	–
CI500 Series Sterile Replacement Magnet	Z179608	–	–

* Supplied with implant; not available separately

Items used with the Cochlear Nucleus CI532 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.

Electrode Claw (Straight) Z30090

Aids insertion of the Straight electrode into the cochlea.

Single-use sterile

These items are supplied sterile for single-use only.

Warning

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

CI500 Series Non-Magnetic Plug	Z146624

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

The non-magnetic plug is not intended for use unless required for multiple MRIs. If only a single MRI is required the magnet recess can remain empty.

For more information see *MRI safety information* on page 78.

CI500 Series Sterile Replacement Magnet	Z179608

Used to replace a non-magnetic plug or fill an empty magnet recess after MRI examinations are complete.

For more information see *MRI safety information* on page 78.

Slim Modiolar Electrode Sheath	P1291522

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

Depth Gauges

Contour Advance Depth Gauge Z179994	Depth Gauge (Straight) Z60006
	

Depth gauges are typically used in the sterile field when:

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

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

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

Cochleostomy Sizing Tool Z341279

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

CI500 Series Sterile Silicone Implant 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 45.

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 Implant Template	Z179609

Used to determine or 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 sleeve. Use without a sterile sleeve could cause infection.

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:

Where a surgical instrument is mentioned in the procedure, see *Surgical instruments and accessories* on page 35.

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 Sterile Silicone Implant Template is packaged with each implant. For warnings and more information see *CI500 Series Sterile Silicone Implant Template* on page 41.

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.

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 or 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.

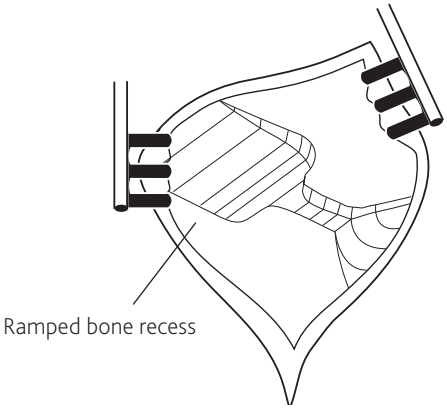
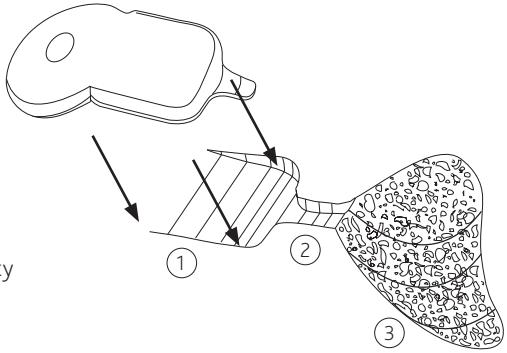


Figure 4: Ramped bone recess

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 5: 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 5*). 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 47), 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 6: 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 (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 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 59.

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

To avoid residual hearing loss or vestibular issues, 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.

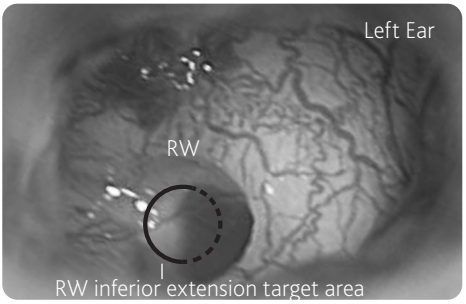


Figure 7: Round window target area

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 59.

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 mm–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 59.

4. 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 Series Sterile Silicone Implant Template* on page 45.

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

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 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 or pericranial pocket between the tie-down holes.

   For information on correct implant orientation see *Device description* on page 32.

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

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

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

Overview of insertion steps

Figure 8: 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 or cochleostomy opening. You should be able to advance the electrode without resistance. Do not use force.

Warning

If the cochleostomy or 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 or 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.

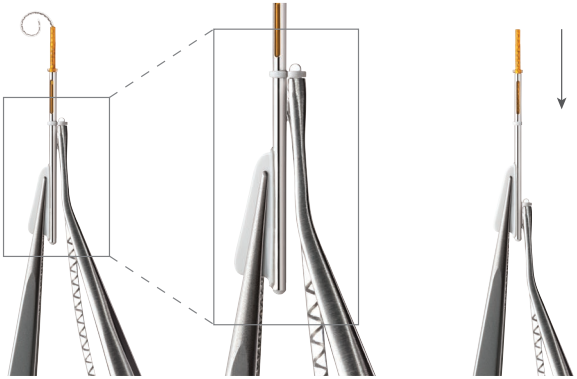


Figure 9: Straightening the intracochlear electrode

D. Hold the sheath handle with forceps and direct the sheath and electrode array towards the opening of the cochleostomy or 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 or round window.

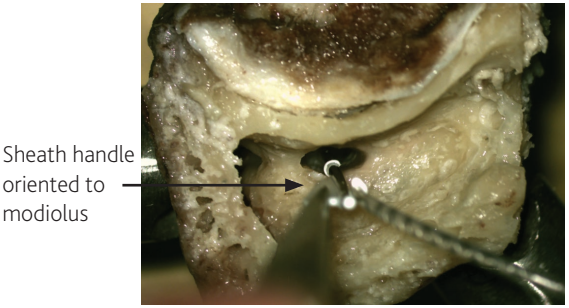


Figure 10: Inserting sheath tip into cochleostomy or round window opening (right ear temporal bone shown)

⚠ Caution

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

Note

- 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.

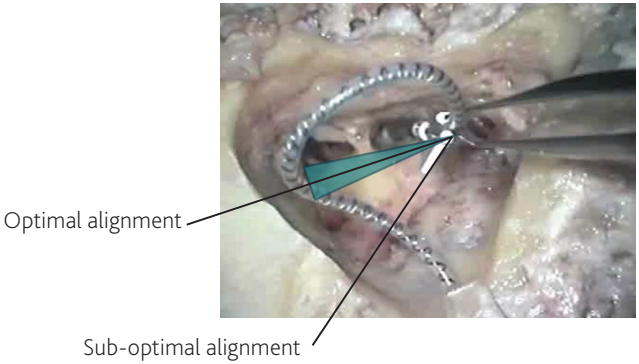


Figure 11: Aligning handle along medial plane of scala tympani

- **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 or 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 12: Electrode tip visible from end of sheath before reaching cochleostomy entrance

Warning

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

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

  If the cochleostomy or 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.

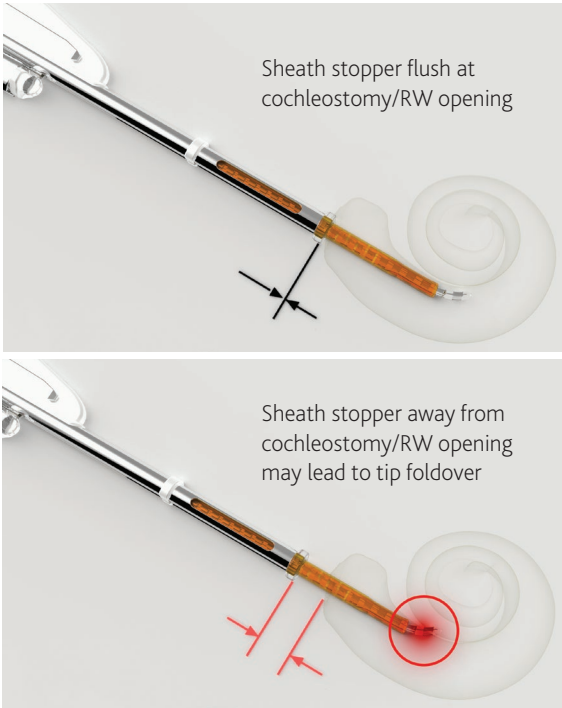


Figure 13: Sheath not flush at opening may result in poor insertion

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.

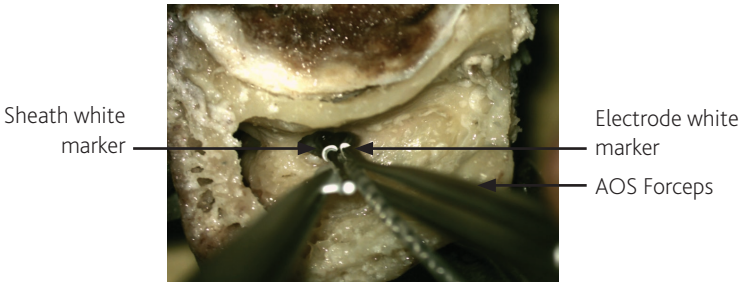


Figure 14: Advancing electrode into cochlea (right ear temporal bone shown)

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.

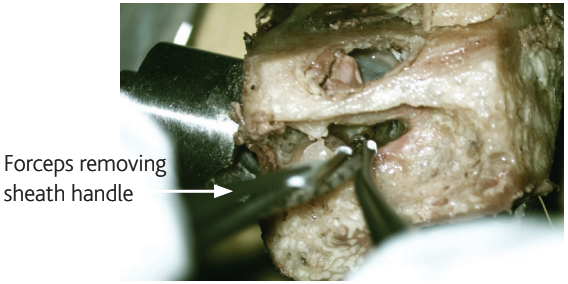


Figure 15: Removing sheath with forceps

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 or round window opening, a full insertion has been performed.

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

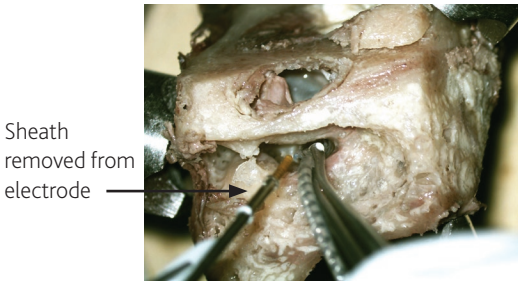


Figure 16: Electrode array fully inserted into cochlea and sheath removed

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 68.

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.

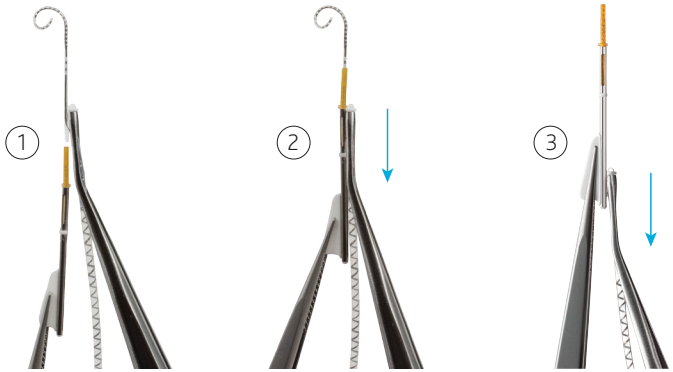


Figure 17: Guiding the electrode into the sheath and retracting the electrode array

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.

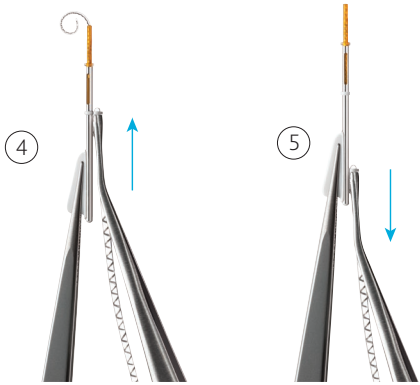


Figure 18: Sliding electrode through sheath and retracting

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.

   Warning

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

   Note

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

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

   Note

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

Confirmation of electrode placement

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

For information on Stenver's view, contact Cochlear or 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 sleeve.

   Warning

   If using the Intraoperative Spacer, place the coil on top of the Intraoperative Spacer in the sterile sleeve.

3. Place the external coil over the implant magnet.

   Note

   - The transmitting range of the cochlear implant is 1 mm to 10 mm.
   - The cochlear implant may not function properly if the processor coil is placed directly on top of the receiver/stimulator.
   - Methods to determine that the cochlear implant is functioning properly include impedance measurement using a Cochlear proprietary programming system.

14. Closure

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

Post-operative management

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

Fitting the sound processor

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

Registering the implant

Registration form

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

Patient implant card

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

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

Identifying the implant

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

Explanting the implant

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

1. Contact Cochlear to order a Retrieved Device Kit. The kit must be used to transport the explanted device to Cochlear.
2. Read the instructions provided with the kit.
3. Before explanting the device, examine it for any defects. Note these on the form provided with the kit.
4. Try to keep the explanted device intact and undamaged. To assist in removing the device undamaged you can cut the intracochlear electrode lead (see *Cutting the intracochlear electrode lead* on page 77).
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.

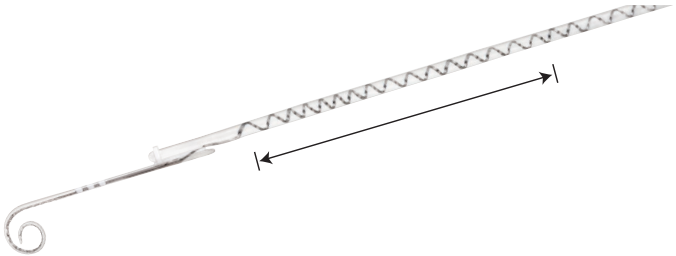


Figure 19: Where to cut electrode lead if required during explantation

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 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.

Clinicians and recipients should weigh the benefits and risks of completing an MRI scan at 1.5 T and choose one course of action:

1. Keep the magnet in place and use an MRI Kit.
2. Remove the implant magnet and replace it via surgical procedures.
3. Do not perform the MRI scan.

Full MRI safety information should be reviewed prior to determining the most appropriate course of action. Safety information is available:

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

All external components of the Cochlear implant system (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 Cochlear Disk Retainer to hold their external transmitter coil in place. Disk retainers 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 grey ring (denoting polarity) facing up (see magnet images in ***Replacing the magnet*** on page 84). 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 84.

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 81) 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 84.

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 disk retainer to hold their external transmitter coil in place. Disk retainers 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 81) 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 20: 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 84.

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 81) 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 grey ring (denoting polarity) facing up, as shown below.

Figure 21: CI500 Series magnet with grey ring 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.
- Some recipients may have a magnet with a Cochlear logo.

Figure 22: CI500 Series magnet with Cochlear logo facing upwards

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.

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 the package 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.

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	0.15 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 • Cylindrical electrode 0.6 mm (typical) diameter with hemispherical tip, on a lead 60 mm in length

Receiver/Stimulator	
Dimensions	Case: 24 mm x 23 mm x 3.9 mm Coil: 31 mm diameter x 3.7 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 / 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 mm 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 and common ground modes
Impedance measurement accuracy	12.7% 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
Titanium	Receiver/stimulator case 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

<table>
<tr><th>Emission test</th><th>Compliance</th><th>Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td rowspan="2">Not applicable</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td></tr>
</table>

Table 6: Electromagnetic emissions

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±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 Radiated RF IEC 61000-4-3	Not applicable 10 V/m 80 MHz to 2.7 GHz	Not applicable 20 V/m 80 MHz to 3.0 GHz	See *Warnings and Cautions for device use* on page 6, and *Guidance* on page 91.

Table 7: 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 or 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 8: 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 and consult instructions for use
	Consult instructions for use
UDI	Unique Device Identifier
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
2	Do not re-use
2 STERILIZE	Do not resterilise
	Date of manufacture
	Manufacturer
	Use-by date
	Single sterile barrier system with protective packaging inside
	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 0123	CE registration mark with notified body number
MD	Medical Device
MR	MR Conditional

Hear now. And always

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

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