CI532P

Cochlear™

Nucleus® CI532P cochlear implant with Slim Modiolar electrode and silicone pedestal

Physician's Guide

Canada

Hear now. And always

Cochlear®

About this guide

This guide applies to the Cochlear™ Nucleus® CI532P 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.

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 CI532P implant is MR Conditional. MRI is contraindicated except under specific circumstances. See *MRI safety information* on page 68.

Cautions

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

Note

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

Notes

Intended use and indications

Intended use

Cochlear Nucleus CI500 Series implants are prescription only, single use devices intended for long term implantation under the skin in the mastoid region of either side of the head.

Indications

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

Adults

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

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

Children

The cochlear implant system is intended for use in children 12 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids.

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

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

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

Health Canada has not authorized the use of this device for individuals with residual hearing loss less than 50 dB HL.

Contraindications

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

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

Adverse effects

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

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

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

Meningitis

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

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

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

Summary of adverse events

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

Adults

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

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

Medical/Surgical complications

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

Device-related complications

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

Children

Pediatric safety data are based on a total of 150 children implanted with the Cochlear Nucleus 24 cochlear implant during the clinical investigation. 24 patients experienced 27 medical/surgical or device-related complications. Nine of the 27 complications were medical/surgical in nature and the remaining 18 were device-related. 24 of the complications resolved without surgical or extensive medical intervention.

Medical/Surgical complications

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.

Device-related complications

No device failures or other serious device malfunctions were observed during this study. 13 patients experienced electrode faults (short-circuit or open-circuit electrodes) on one or more electrodes. All of these cases were resolved through reprogramming. One patient experienced non-auditory sensations during psychophysical testing. This case was resolved through reprogramming. One patient experienced an unanticipated overstimulation. This complication was resolved through replacement of external equipment.

Three patients experienced mild skin reactions to the processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

Loss of residual hearing

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

Device description

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

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

Implanted component

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

External components

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

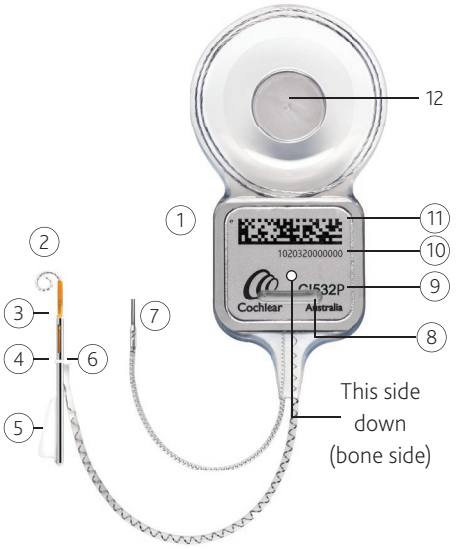
The system is programmed by a Cochlear proprietary programming system.

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

The Cochlear™ Nucleus® CI532P cochlear implant with Slim Modiolar electrode and silicone pedestal

The CI532P 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 CI532P 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 Silicone pedestal
9 Model name
10 Serial number
11 Barcode
12 Magnet (blank on bone side)

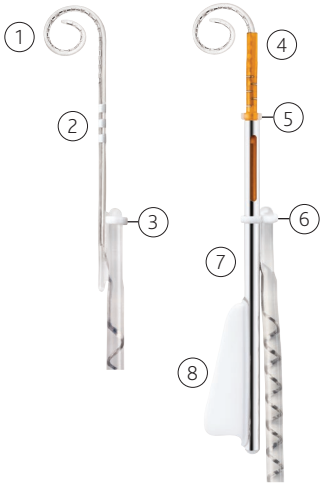
Figure 1: CI532P cochlear implant with Slim Modiolar electrode (bone side)

1 Magnet (grey ring on skin side)

2 Extracochlear electrode (plate) to face upwards/skin

3 Intracochlear electrode with sheath

Figure 2: CI532P 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

Notes

Surgical instruments

Instruments supplied in implant kit

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

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

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

Warning

- For temporary use only. Not for implantation.
- Supplied sterile. Sterilised in ethylene oxide. Do not resterilise.
- Single-use item. Do not use more than once. Re-use could cause infection.
- Do not use if packaging is damaged.
- Do not use if instruments become non-sterile e.g. if dropped or mishandled in theatre after removal from packaging.
- After surgery it is advisable to dispose of the instruments, even if not used.
- Dispose of instruments according to your institution's policy for disposal of biohazardous waste.
- Use with CI532 cochlear implants only.

CI500 Series Sterile Silicone Implant Template

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

One Sterile Silicone Implant Template is packaged with each implant. For more information see warnings above and *2. Opening the Sterile Silicone Implant Template* on page 30.

Figure 4: CI500 Series Sterile Silicone Implant Template

Cochleostomy Sizing Tool

Packed in the implant tray (white seal).

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

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

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

Figure 5: Cochleostomy Sizing Tool

Surgical Instrument Kit for CI500 Series

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

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

BTE Template

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

Figure 6: BTE Template

Pedestal Recess Gauge (Z335623)

Used to mark the pedestal well on the skull, and check the depth of the well after drilling.

Figure 7: Pedestal Recess Gauge

CI500 Series Recess Gauge

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

Figure 8: CI500 Series Recess Gauge

CI500 Series Implant Template

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

Figure 9: CI500 Series Implant Template

Contour® Electrode Claw

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

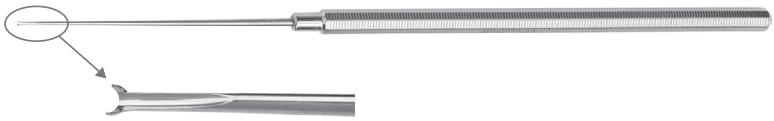


Figure 10: Contour Electrode Claw

AOS™ (Advance Off-Stylet®) Forceps

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

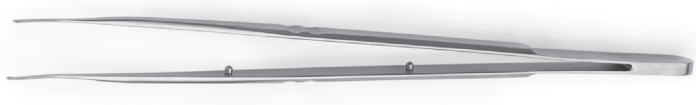


Figure 11: AOS Forceps

Other instruments

Surgical instruments that can be ordered individually are described below.

Spacer for Intraoperative Testing

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

The Spacer is non-sterile.

Caution

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

Figure 12: Spacer

CI500 Series Non-sterile Silicone Implant Template

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

Warning

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

Figure 13: CI500 Series Non-sterile Silicone Implant Template

Slim Modiolar Electrode Sheath

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

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

Figure 14: Slim Modiolar Electrode Sheath

Surgical procedure

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

The surgical procedure includes the following:

1. "Pre-incision: non-sterile field" – page 29
2. "Opening the Sterile Silicone Implant Template" – page 30
3. "Incision and periosteal pocket" – page 31
4. "Mastoidectomy and preparing the bone recess" – page 32
5. "Drilling tie-down holes" – page 34
6. "Opening the facial recess (Posterior Tympanotomy)" – page 35
7. "Preparing the round window or cochleostomy" – page 36
8. "Inspecting the implant, electrodes and sizing tool" – page 40
9. "Positioning and securing the implant" – page 41
10. "Securing the extracochlear electrode" – page 42
11. "Inserting the intracochlear electrode" – page 43
12. "Securing and sealing the intracochlear electrode" – page 55
13. "Performing intraoperative measurements" – page 57
14. "Closure" – page 58

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments*** on page 22.

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 Sterile Silicone Implant Template

One Sterile Silicone Implant Template is packaged with each implant. For warnings and more information see *Instruments supplied in implant kit* on page 22.

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/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 bone 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 location of the pedestal.
2. Drill an appropriate well to accommodate the pedestal dimensions. Use the Pedestal Recess Gauge to check the well.
3. Use the Implant Template or Recess Gauge to mark the exit of the electrode.
4. Drill a channel to the mastoid cavity. The channel will help protect the electrode against trauma.

5. Drilling tie-down holes

1. Using the implant seat for orientation (see *The bone recess* on page 32), 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 15: 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 CI532P 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 43.

Caution

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

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

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

Warning

Do not suction the perilymph.

Round window

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

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

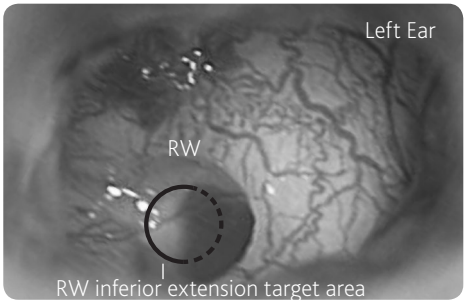


Figure 16: Round window target area

2. Remove the false membrane.

Warning

Do not open the round window membrane until immediately before insertion of the electrode as described in *11. Inserting the intracochlear electrode* on page 43.

Cochleostomy

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

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

2. Perform a cochleostomy into the scala tympani using a diamond burr at low speed.

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

   ### Warning

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

   ### Caution

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

3. Drill sufficient bone to expose at least 0.8–1.0 mm of endosteum.

   Warning

   To avoid risk of contamination do not open the endosteum until immediately before insertion of the electrode as described in *11. Inserting the intracochlear electrode* on page 43.

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 Sterile Silicone Implant Template* on page 30.

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

Warning

From this point, do not use monopolar electrosurgical instruments on the neck and head of the patient.

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

Caution

To avoid damage to the cochlear implant:

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

9. Positioning and securing the implant

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

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

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

   Move the knot to the edge of the cochlear implant.

   Note

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

10. Securing the extracochlear electrode

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

Caution

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

11. Inserting the intracochlear electrode

Before insertion

The following should be performed immediately before inserting the electrode.

Round window

Make a straight incision the width of the round window.

Cochleostomy

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

Warning

Do not suction the perilymph.

Overview of insertion steps

Figure 17: Steps for inserting electrode into the cochlea

Note

To prevent movement of the electrode in the cochlea:

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

Caution

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

Warning

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

Insertion

To insert the intracochlear electrode into the cochlea:

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

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

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

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

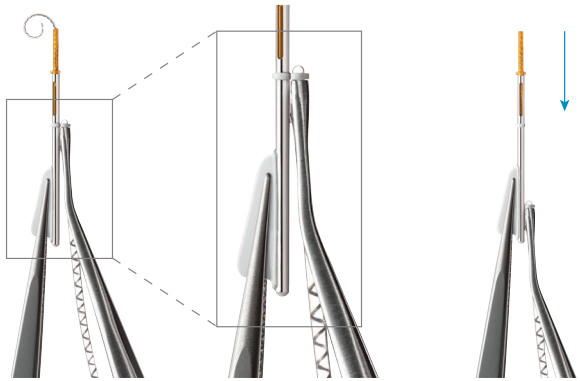


Figure 18: Straightening the intracochlear electrode

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

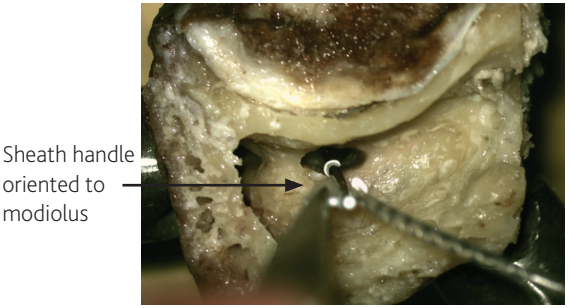


Figure 19: Inserting sheath tip into cochleostomy/round window opening (right ear temporal bone shown)

Caution

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

Notes

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

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

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

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

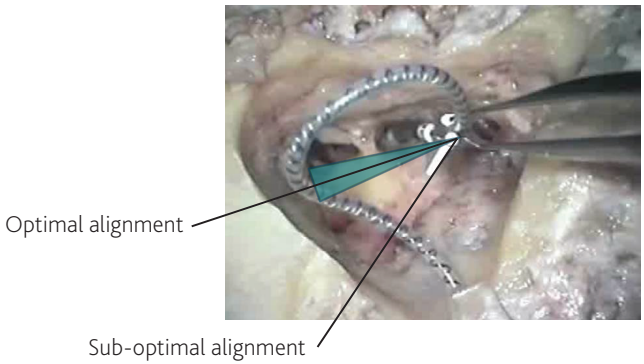


Figure 20: Aligning handle along medial plane of scala tympani

- Ensure the electrode remains in the sheath during insertion.

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

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

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

Figure 21: Electrode tip visible from end of sheath before reaching cochleostomy entrance

Warning

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

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

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

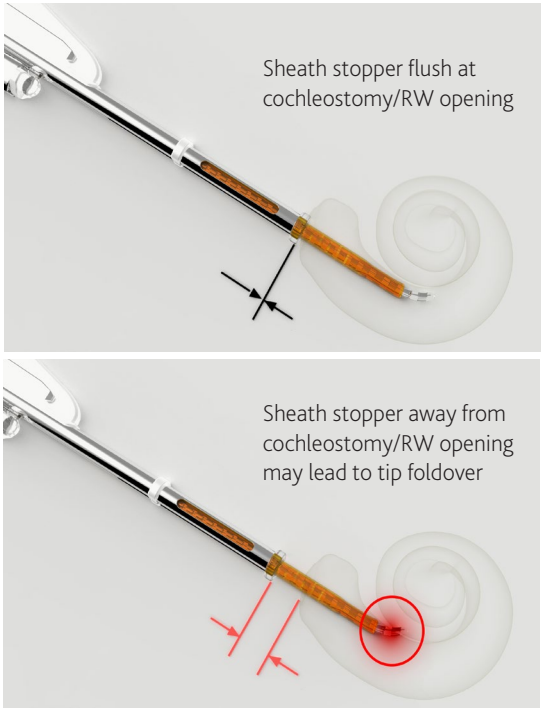


Figure 22: Sheath not flush at opening may result in poor insertion

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.

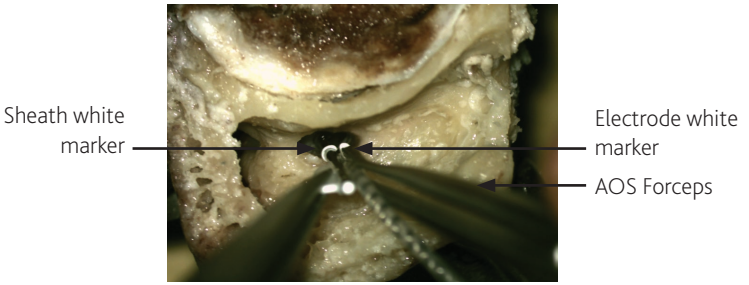


Figure 23: Advancing electrode into cochlea (right ear temporal bone shown)

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.

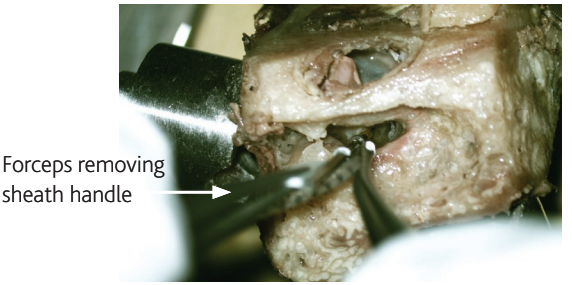


Figure 24: Removing sheath with forceps

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

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

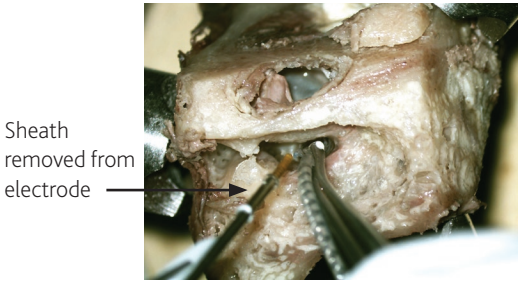


Figure 25: Electrode array fully inserted into cochlea and sheath removed

Warning

- Ensure the sheath is fully removed. The sheath needs to be completely removed from the electrode and **not** left in place after the procedure is complete.
- Keep the sheath in the sterile field in case it is needed for a second insertion attempt. See *Reloading the sheath* on page 52.

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.

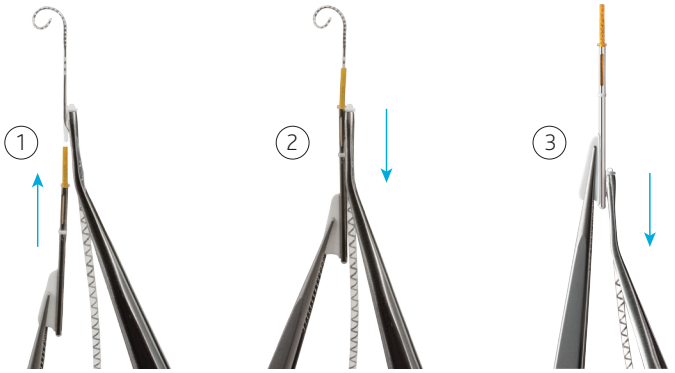


Figure 26: Guiding the electrode into the sheath and retracting the electrode array

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.

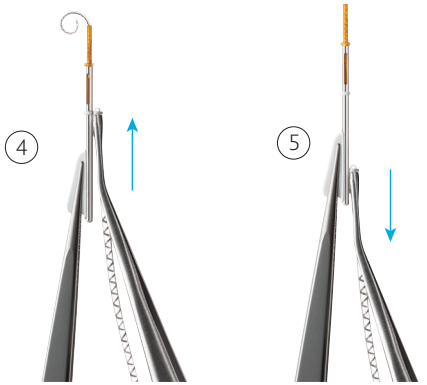


Figure 27: Sliding electrode through sheath and retracting

Caution

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

12. Securing and sealing the intracochlear electrode

Warning

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

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

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

   Note

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

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

   Note

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

Confirmation of electrode placement

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

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

13. Performing intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

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

Warning

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

3. Place the external coil over the implant magnet.

Note

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

14. Closure

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

Notes

Notes

Notes

Post-operative management

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

Fitting the sound processor

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

Registering the implant

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

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

Identifying the implant

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

Cochlear Nucleus CI24RE Series implant

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

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

The characters at the base ('C13T' in Figure 28 below) indicate the following.

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

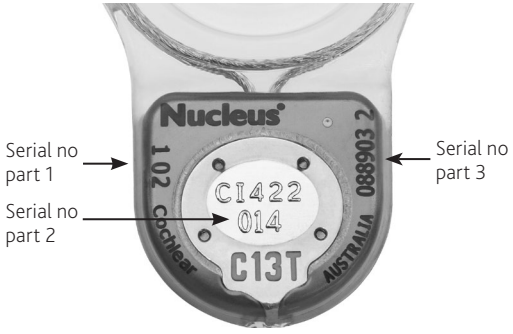


Figure 28: CI422 radiopaque label and serial number

The serial number is in three parts, as labelled in Figure 28, and is read from left to right.

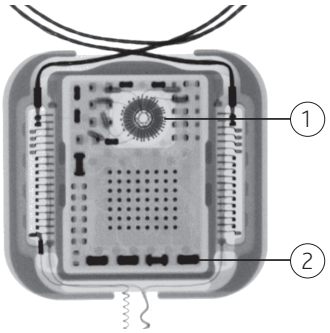
Serial number part 1	Serial number part 2	Serial number part 3
102	014	0889032

Cochlear Nucleus CI500 Series implant

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

Cochlear CI500 Series implants have:

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



1 Round shape at coil exit end

2 Four large components at electrode exit end

Figure 29: Plain X-ray of CI500 Series implant

Explanting the implant

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

1. Contact Cochlear to order a Retrieved Device Kit. The kit must be used to transport the explanted device to Cochlear.
2. Read the instructions provided with the kit.
3. Before explanting the device, examine it for any defects. Note these on the form provided with the kit.
4. Try to keep the explanted device intact and undamaged. To assist in removing the device undamaged you can cut the intracochlear electrode lead (see *Cutting the intracochlear electrode lead* on page 66).
5. If the intracochlear electrode lead is removed from the cochlea, place it in the kit, even if it is damaged.
6. Return the kit containing the explanted device to the Cochlear address nearest you.

Cutting the intracochlear electrode lead

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

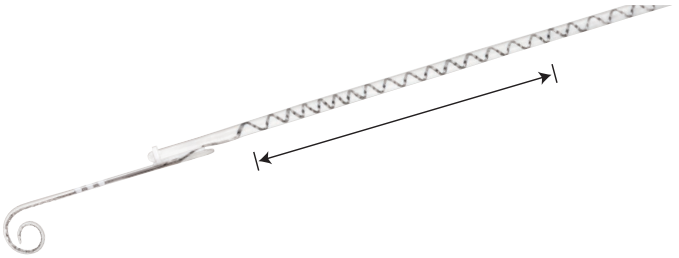


Figure 30: Where to cut electrode lead if required during explantation

Reporting problems

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

Notes

MRI safety information

The Cochlear Nucleus CI532P implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

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

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

Removing the magnet

Caution

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

Removing the magnet before implantation

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

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

The replacement procedure should take place under sterile conditions.

To replace the magnet before implantation:

1. In sterile conditions, remove the cochlear implant from its sterile packaging and place it on a flat and stable surface, with the magnet's Cochlear logo or grey ring (denoting polarity) facing up (see magnet images in ***Replacing the magnet*** on page 74). 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.

When there is no further need for MRI examinations, replace the magnet following the steps in ***Replacing the magnet*** on page 74.

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 71) 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 74.

Multiple MRI

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

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

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

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

Inserting a non-magnetic plug

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

1. Under sterile conditions, make a small incision (see ***Removing the magnet after implantation*** on page 71) 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 31: CI500 Series non-magnetic plug

Caution

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

3. Close the wound in layers.
4. When MRI is no longer a regular necessity, insert a replacement magnet by following the steps in ***Replacing the magnet*** on page 74.

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 71) exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a new sterile replacement magnet, available from Cochlear, with the Cochlear logo or grey ring (denoting polarity) facing up, as shown below.

Figure 32: CI500 Series magnets facing upwards

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

Caution

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

Note

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

4. Close the wound in layers.

For additional information about magnet removal, contact Cochlear.

Notes

How the implant is supplied

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

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

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

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

Storage and handling

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

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

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

Notes

CI532P 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: 23 mm x 23.5 mm x 3.9 mm Coil: 31 mm diameter x 3.7 mm thick
	Silicone Pedestal: 10 mm x 2 mm x 2 mm
Volume	3.9 cm^3 without lead
Weight without sheath	9 g including electrode arrays

Operating characteristics	
Power and data	Received by 5 MHz inductive link from sound processor headset coil
Current	Biphasic pulses
Stimulation mode	Monopolar, bipolar or common ground
Stimulus amplitudes	Programmable from 0 µA to 1750 µA nominal at 37 °C
Maximum stimulus amplitude	Median: 1750 µA Range: 1575 µA to 1925 µA as measured according to EN 45502-2-3
Output signal on a 1 kΩ resistor	Amplitude 1750 µA, pulse width 400 µs
Stimulus duration	Programmable from 9.6 µs to 400 µs per phase
Maximum stimulus pulse width	Median: 400 µs Range: 398 µs to 410 µs as measured according to EN 45502-2-3
Transmitting range	1 to 10 mm

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

Materials in contact with body tissues	
Silicone elastomer	Lead and receiver/stimulator protective coating and insulation
Titanium	Receiver/stimulator case Magnet case
Platinum	Electrode contacts

General information

Warranty

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

Symbols

The following symbols may appear on your implant packaging:

	Fragile, handle with care
	Do not use if package is damaged
	Refer to instruction manual
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Do not re-use
	Do not resterilise
	Date of manufacture
	Manufacturer
	Use-by date
	Temperature limits
	Keep dry
	Sterilised using ethylene oxide
	Caution: US law restricts this device to sale by, or on the order of, a physician
	Catalogue number
	Serial number

LOT	Batch code
EC REP	Authorised representative in the European Community
MR	MR Conditional
CE 0123	CE registration mark with notified body number

Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user/recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on www.cochlear.com or request a copy from Cochlear at the address nearest you.

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

Hear now. And always

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