CI612

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

Physician's Guide

Canada

Hear now. And always

Cochlear®

About this guide

This guide applies to the Cochlear™ Nucleus® CI612 cochlear implant, which is a CI600 Series implant.

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

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

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

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

Symbols used in this guide

Note

Important information or advice.

Caution (no harm)

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.

Warning (harmful)

Potential safety hazards and serious adverse reactions.

Could cause harm to person.

Contents

Warnings and Cautions for device use

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

Warnings

Pre-operative

- **Meningitis** is a known risk of inner ear surgery. You should counsel candidates of this risk and determine their immunisation status for micro-organisms that cause meningitis.
- **Wound infection** after cochlear implant surgery or explantation may be prevented by administering broad-spectrum antibiotic before and during surgery.
- The implant is sterilised using **ethylene oxide (EtO)**. After the sterilisation process, residual EtO is less than 0.4 mg per device. This residual level is suitable for a recipient with a body weight of 7 kg or greater.*
- 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.

* Calculated with guidance from EN ISO 10993-7.

Medical treatments generating induced currents, heat and vibration

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

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

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

  Do not use:

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

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

  – **neurostimulation** directly over the implant.

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

  Do not use:

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

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

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

Magnetic Resonance Imaging (MRI)

The Cochlear Nucleus CI612 implant is **MR Conditional**. MRI is contraindicated except under specific circumstances.
See *MRI safety information* on page 52.

Cautions

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

Note

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

Intended use and indications

Intended use

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

Indications

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

Health Canada has not authorised the use of this device for individuals with residual hearing loss less than 50 dB HL in the ear to be implanted.

Bilateral sensorineural hearing loss

Adults

The CI612 cochlear implant with Contour Advance® electrode is intended for use in individuals 18 years of age or 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 CI612 cochlear implant with Contour Advance electrode 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 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 month 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 month to six month hearing aid trial is recommended for children without previous aided experience.

Unilateral hearing loss (UHL) / single sided deafness (SSD)

Adults and children

The CI612 cochlear implant with Contour Advance electrode 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
- Weight < 7 kg, due to the potential presence of residual ethylene oxide after sterilisation of the device. See *Warnings and Cautions for device use* on page 6.

For individuals with single sided deafness the following contraindication is 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 sided 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 5 years of age.

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.

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 software.

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

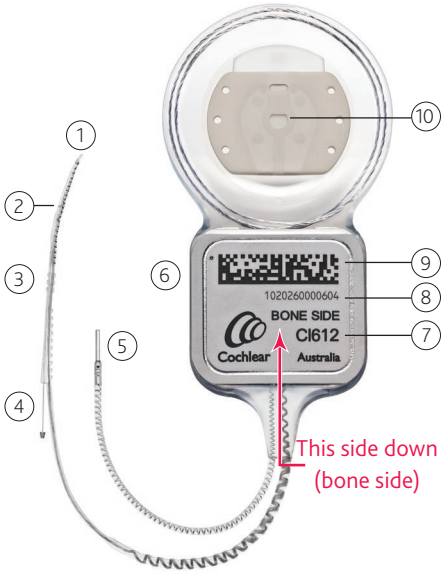
New features

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

Figure 1: CI612 cochlear implant with magnet cassette partially removed from pocket

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

The CI612 implant is a CI600 Series implant.

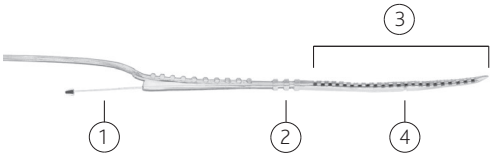


1 Intracochlear electrode (shaped to follow curve of cochlea when stylet is removed)
2 White marker to facilitate AOS insertion
3 Ribs indicating electrode insertion depth
4 Stylet
5 Extracochlear electrode
6 Receiver/stimulator (printed information on bone side)
7 Model name
8 Serial number
9 Barcode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

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

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

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

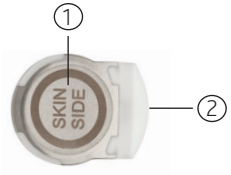


1 Stylet
2 Ribs indicating insertion depth
3 Intracochlear electrode with 22 half-band contacts
4 White marker to facilitate AOS insertion

Figure 4: Contour Advance electrode with stylet

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

Figure 5: Contour Advance electrode with stylet removed



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

Figure 6: Cochlear Nucleus Magnet Cassette (skin side)

Surgical instruments and accessories

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

All items except the Sterile Silicone 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	–	–
Accessories			
Non-Magnetic Cassette	P782484	–	–
Replacement Magnet Cassette	P782485	–	–

* Supplied with implant; not available separately

Items used with the Cochlear Nucleus CI612 cochlear implant are referenced in the *Surgical procedure* and *MRI safety information* sections of this guide.

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

Warning

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

Reusable after reprocessing

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

AOS™ Forceps for the Contour Advance® Electrode — Z60770

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

Caution

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

BTE Template — Z33011

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

CI500 Series Recess Gauge Z139274

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

CI500 Series Implant Template Z139273

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

Contour Advance Electrode Claw Z33021

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

Electrode Claw (Straight) Z30090

Aids insertion of the Straight electrode into the cochlea.

Single-use sterile

These items are supplied sterile for single-use only.

Warning

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

Non-Magnetic Cassette	P782484

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

For more information see *MRI safety information* on page 52.

Replacement Magnet Cassette	P782485

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

For more information see *MRI safety information* on page 52.

Note

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

- When marking the incision site, the silicone carrier can be used as a template. For details see *Removing and replacing the magnet cassette or non-magnetic cassette after implantation* on page 60.

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*.

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 30.

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/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 sound 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 CI612 cochlear implant.

The surgical procedure includes the following:

1. Pre-incision: non-sterile field – page 29
2. Opening the CI500 Series Sterile Silicone Implant Template – page 30
3. Incision – page 31
4. Mastoidectomy and preparing the bone recess – page 32
5. Drilling tie-down holes – page 35
6. Opening the facial recess – page 36
7. Preparing the cochleostomy – page 37
8. Inspecting the cochlear implant and electrodes – page 39
9. Positioning and securing the implant – page 40
10. Securing the extracochlear electrode – page 41
11. Inserting the intracochlear electrode – page 42
12. Securing and sealing the intracochlear electrode – page 45
13. Performing intraoperative measurements – page 47
14. Closure – page 48

Where a surgical instrument is mentioned in the procedure, see ***Surgical instruments and accessories*** on page 19.

1. Pre-incision: non-sterile field

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

   Note

   For bilateral patients, position the second receiver/stimulator so that it is symmetrical with the first.
3. Mark the incision with a marking pen. Allow at least 15 mm between the implant and the incision.

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

2. Opening the CI500 Series Sterile Silicone Implant Template

One CI500 Series Sterile Silicone Implant Template is packaged with each implant. For more information on use of the template see ***CI500 Series Sterile Silicone Implant Template*** on page 26.

Non-sterile field

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

   Warning

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

Sterile field

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

   Note

   Keep the cochlear implant tray (white seal) to one side, within the sterile field, with the seal intact until later in the surgery.
5. Lift the Sterile Silicone Implant Template from the tray.

3. Incision

Warning

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

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

4. Mastoidectomy and preparing the bone recess

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

The cortical mastoidectomy

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

Note

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

The bone recess

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

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

Warning

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

To drill the bone recess:

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

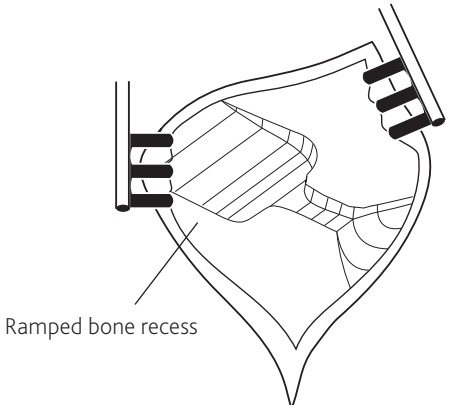
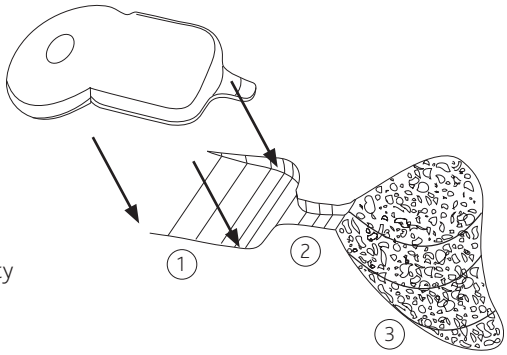


Figure 7: Ramped bone recess

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



1 Ramped bone recess
2 Channel
3 Mastoidectomy cavity

Figure 8: Ramped bone recess, electrode channel and mastoidectomy

4. Place the Implant Template or Recess Gauge in the bone recess and use it to mark the exit of the electrode.
5. Drill a channel to connect the bone recess and mastoid cavity – see Figure 8. The channel will help protect the electrode against trauma.
6. Use the Recess Gauge to check the position and depth of the electrode exit.

5. Drilling tie-down holes

1. Using the implant seat for orientation (see *The bone recess* on page 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 9: Tie-down holes for CI600 Series implants

Warning

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

6. Opening the facial recess

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

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

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

7. Preparing the cochleostomy

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

Cochleostomy

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

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

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

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

   Warning

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

   Caution

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

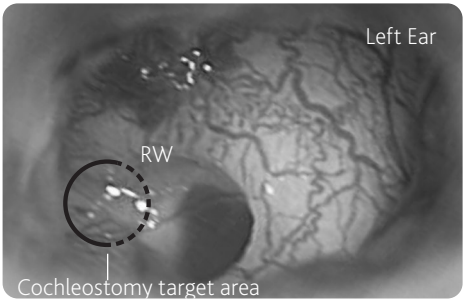


Figure 10: Cochleostomy target area

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

Warning

To avoid risk of contamination do not open the endosteum until immediately before insertion of the electrode as described in *11. Inserting the intracochlear electrode* on page 42.

8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked see *2. Opening the CI500 Series Sterile Silicone Implant Template* on page 30.

Sterile field

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

Warning

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

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

Caution

To avoid damaging the cochlear implant:

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

9. Positioning and securing the implant

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

   For information on correct implant orientation see *Device description* on page 15.

   Caution

   To avoid damage, do not bend the implant coil.

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

   Move the knot to the edge of the cochlear implant.

   Note

   Do not suture directly over the magnet cassette cover as this may obstruct potential cassette removal – see *Figure 15* on page 55.

10. Securing the extracochlear electrode

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

Caution

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

11. Inserting the intracochlear electrode

Warning

- Damage to the electrode and the cochlea may be caused if the stylet is reinserted. Do not reinsert the stylet in order to reinsert or reposition the electrode.
- In the event of suboptimal placement, it is recommended to remove the electrode and use the backup implant instead.

Caution

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

Note

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

Before insertion

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

Inserting via a cochleostomy

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

Warning

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

Advance Off-Stylet® (AOS™) insertion

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

1. Grasp the protective tube (in the end section) and carefully remove the tube from the electrode. Do not squeeze, stretch or bend the electrode.
2. Orientate the electrode so that its curve will follow the cochlear spiral.
3. Guide the tip toward the cochleostomy, using the claw or other blunt tip surgical instrument. Angle the electrode toward the floor of the scala tympani. Ensure the half-band electrode contacts remain oriented toward the modiolus.
4. Insert the electrode until the white marker (7.6 mm from tip) is at the cochleostomy (see ***Figure 11*** on page 44).
5. Hold the stylet stationary with jeweller's forceps and hold the electrode at the ribs with AOS forceps. Advance the electrode off the stylet and into the cochlea until the third (most proximal) rib is at the cochleostomy (Figures B, C and D).
6. Remove the remainder of the stylet. Then pass the stylet out of the surgical field.

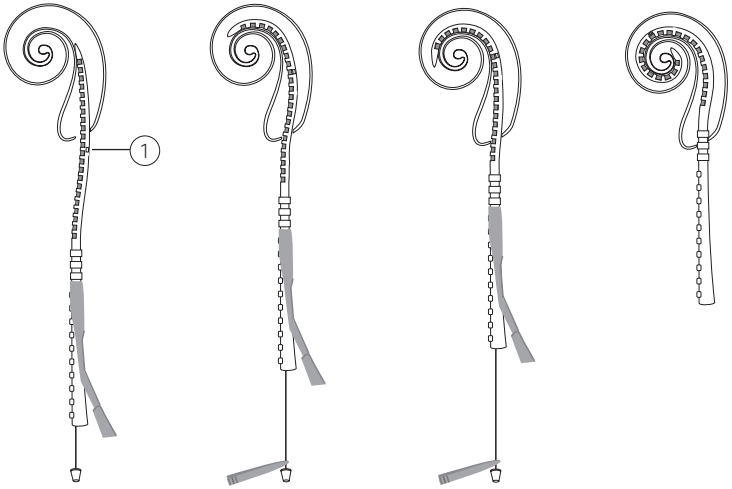


Figure 11: AOS Insertion (white marker (1) 7.6 mm from tip, at cochleostomy)

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

12. Securing and sealing the intracochlear electrode

Warning

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

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

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

   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 sound processor coil and cable in a sterile sleeve.

   Warning

   To avoid infection, 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. However, a maximum skin flap thickness of 6 mm to 10 mm is required for good magnet retention.
   - The cochlear implant may not function properly if the sound 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 software.

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 identification card

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

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

Identifying the implant

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

Explanting the implant

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

1. Contact Cochlear to order a Retrieved Device Kit. The kit must be used to transport the explanted device to Cochlear.
2. Read the instructions provided with the kit.
3. Before explanting the device, examine it for any defects. Note these on the form provided with the kit.
4. Try to keep the explanted device intact and undamaged. To assist in removing the device undamaged you can cut the intracochlear electrode lead. See *Cutting the intracochlear electrode lead* on page 51.
5. If the intracochlear electrode lead is removed from the cochlea, place it in the kit, even if it is damaged.
6. Return the kit containing the explanted device to the Cochlear address nearest you.

Cutting the intracochlear electrode lead

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

If required to remove the device without damage, cut the electrode lead before the ribbed portion of the array:

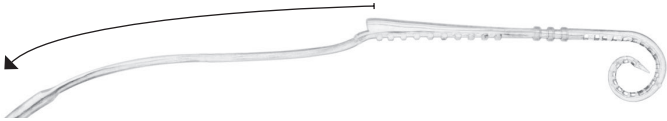


Figure 12: Contour Advance electrode lead cut location for explantation

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

Reporting problems

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

MRI safety information

The Cochlear Nucleus CI612 cochlear implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

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

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

Removing the magnet cassette

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

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

Warning

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

Caution

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

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

Note

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

Replacement magnet cassettes and non-magnetic cassettes

Warning

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

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

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

Figure 13: Nucleus Replacement Magnet Cassette – P782485

Figure 14: Nucleus Non-Magnetic Cassette – P782484

Removing the magnet cassette before implantation

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

The replacement procedure should take place under sterile conditions.

Replacing magnet cassette with non-magnetic cassette before implantation

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

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

Figure 15: CI612 implant with magnet cassette

Warning

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

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

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

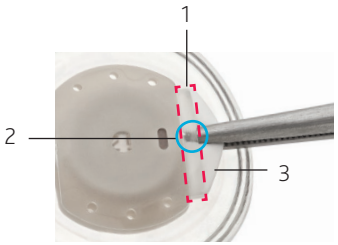


Figure 16: Forceps position on CI612 magnet cassette cover

Caution

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

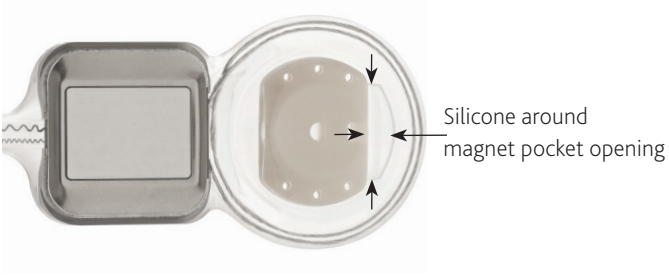


Figure 17: CI612 implant with magnet cassette removed

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

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

Caution

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

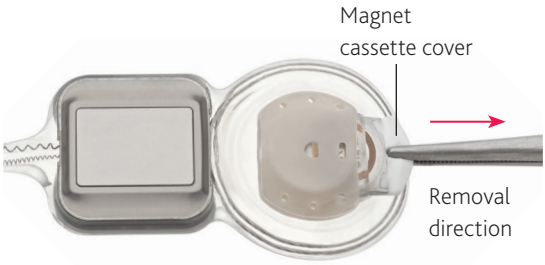


Figure 18: CI612 implant with magnet cassette partially removed

Note

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

Figure 19: Metal tab on magnet cassette

Figure 20: CI612 implant, magnet cassette removal using metal tab

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

Warning

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

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

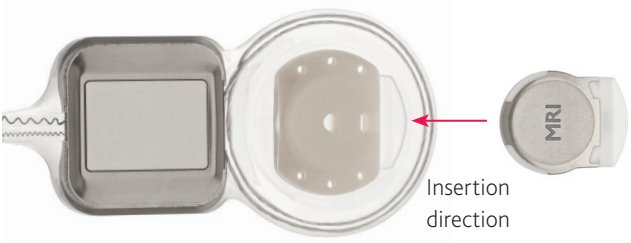


Figure 21: Non-magnetic cassette insertion direction

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

The implant is now ready for implantation.

When there is no further need for MRI examinations, replace the non-magnetic cassette as instructed in ***Removing and replacing the magnet cassette or non-magnetic cassette after implantation*** on page 60.

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

Warning

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

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

Caution

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

Note

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

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

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

Note

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

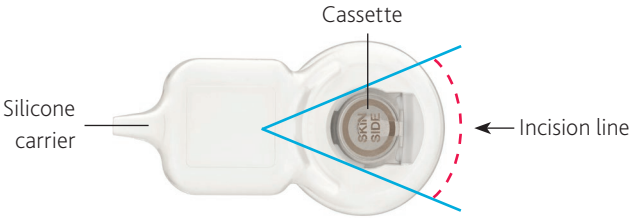


Figure 22: Marking the incision using the silicone carrier

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

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

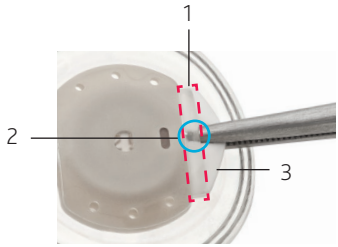


Figure 23: Forceps position on CI612 implant, cassette cover

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

Note

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

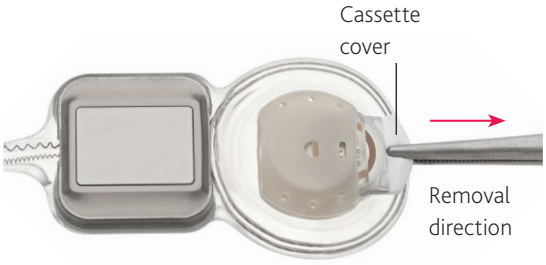


Figure 24: CI612 implant with cassette partially removed

Note

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

Figure 25: Metal tab on cassette

Figure 26: CI612 implant, cassette removal using metal tab

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

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

   Ensure that:

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

   Warning

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

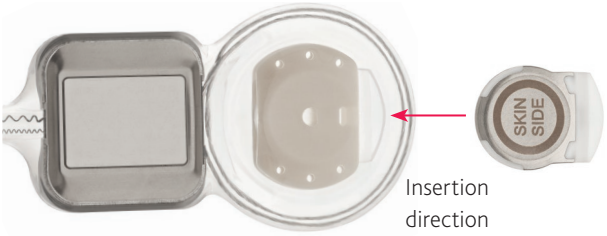


Figure 27: Replacement magnet cassette insertion direction

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

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

How the implant is supplied

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

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

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

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

Transport and handling

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

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

Storage

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

CI612 implant specifications

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

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

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

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

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

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

General information

Warranty

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

Symbols

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

Fragile, handle with care

Do not use if package is damaged and consult instructions for use

Consult instructions for use

Unique Device Identifier

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

	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
	MR Conditional
MD	Medical Device
BONE SIDE	Bone side of implant, to be implanted with this side facing down
SKIN SIDE	Skin side of magnet cassette and replacement magnet cassette

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.

Notes

Hear now. And always

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P1144336-D1144268 V5 2022-05

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