CI24REH

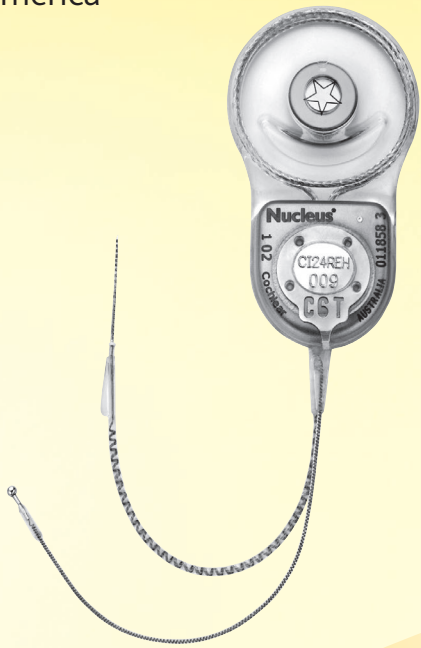
Cochlear™

Nucleus® Hybrid™ L24 cochlear implant

CI24REH

Surgeon's Guide

United States of America



Hear now. And always

Cochlear®

Symbols

Note

Important information or advice. Can avoid inconvenience.

Caution (no harm)

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.

Warning (harmful)

Potential safety hazards and serious adverse reactions.

Could cause harm to person.

This publication sets forth detailed recommended procedures for using Hybrid™ surgical components and instruments. It offers guidance needed for performing the procedure but as with any technical guide, the surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Cochlear™ accepts no responsibility for any adverse outcomes if the surgical components and instruments described here are used with products not recommended by Cochlear. Close cooperation in an interdisciplinary team is essential for a successful outcome. Hands-on surgical workshops are available from Cochlear. Contact your local Cochlear office for details.

Caution

Federal law restricts this device to sale by or on the order of a physician.

Contents

Introduction

This guide explains a surgical procedure for implanting the device. Other surgical approaches and variations are practiced and may be considered more appropriate in certain circumstances. This guide also does not take account of any particular circumstance(s) or factor(s) relevant to an individual patient or case. The appropriate surgical procedure in each case is to be determined by the relevant physician exercising independent medical judgment and after considering all relevant circumstances, factors and information.

⚠ Caution

Information for use and recommended training

Physicians should be very experienced in mastoid surgery and the facial recess approach to the oval window and round window. It is important that physicians be trained in the implantation procedure for the Cochlear™ Nucleus® Hybrid™ L24 cochlear implant. It is strongly recommended that the surgeon work with an experienced team of audiology, speech-language, rehabilitation, education and psychology professionals. It is recommended that audiology professionals attend a training program for this device.

Cochlear Americas conducts periodic training courses. For product-specific information, refer to the Surgeon's Guide supplied with each implant.

Please ensure you are thoroughly familiar with all product labeling.

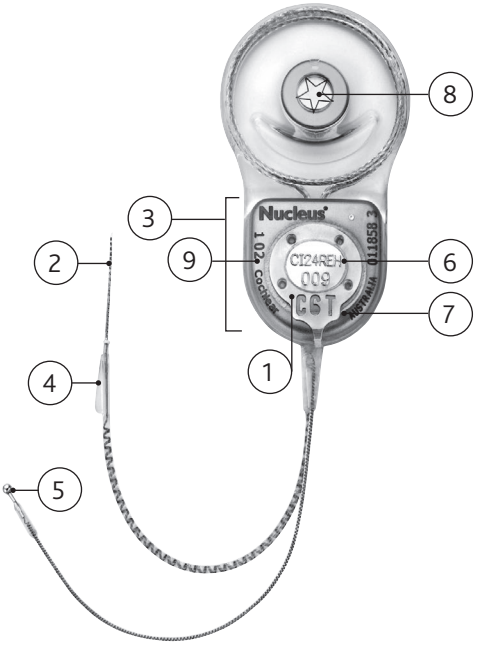
Take care with sharp instruments

When using sharp instruments near the device, take great care to avoid nicking or damaging the case, insulation, or electrode lead.

Please read the Professional Package Insert and the Patient Information. They contain important information on MRI, indications, contraindications, adverse effects, warnings and precautions.

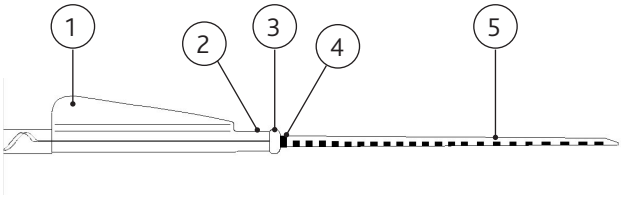
The Cochlear™ Nucleus® Hybrid™ L24 cochlear implant

The Cochlear Nucleus Hybrid L24 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.



1 Receiver/stimulator
2 Intracochlear electrode array
3 Extracochlear electrode (plate)
4 Handle
5 Extracochlear electrode (ball)
6 Model (CI24REH)
7 Radiopaque characters
Manufacturer (C = Cochlear)
Model (6 = Hybrid L24)
Year made (T = 2004 and later)
8 Magnet (star on skin side)
9 Serial no. (e.g. 102 014 0889032)

Figure 1: Hybrid L24 implant (skin side)



1 Handle
2 Platinum stiffener
3 White silicone stopper
4 Platinum band
5 22 modular facing electrodes

Figure 2: Hybrid L24 implant electrode array

Surgical instruments and accessories

Instruments and accessories in this section are appropriate for use with Cochlear Nucleus CI24RE Series implants. For intended use of individual instruments, see descriptions on the following pages.

All items are available to be ordered individually. As indicated below, some items are included in the CI24RE Series Surgical Instrument Kit. An upgrade kit is also available.

Instruments	Product code	CI24RE Series Instrument Kit	CI24RE Series Instrument Upgrade Kit
AOS™ Forceps for the Contour Advance® Electrode	Z60770	✓	–
BTE Template	Z33011	✓	–
CI24RE Series Bone Recess Template	Z60479	✓	✓
CI24RE Series Recess Gauge	Z60480	✓	✓
CI24RE Series Implant Template	Z33019	✓	✓
CI24RE Series Array Exit Marking Template	Z33017	✓	✓
Contour® Electrode Claw	Z33021	✓	✓
CI24RE Series Electrode Claw (Straight)	Z30090	✓	–
Depth Gauge (Straight)	Z60006	–	–
Contour Advance® Depth Gauge	Z179994	–	–
CI24RE Series Non-Sterile Silicone Implant Template	Z33020	–	–
Spacer for Intraoperative Testing	Z33012	–	–
Accessories			
CI24RE Series Non-Magnetic Plug	Z50100	–	–
CI24RE Series Sterile Replacement Magnet	Z50101	–	–

Items used with the Cochlear Nucleus CI24REH cochlear implant are referenced in the *Surgical Procedure* and *Magnetic Resonance Imaging* 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 tips closed and ensure they are aligned and parallel. 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.

CI24RE Series Bone Recess Template Z60479

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

CI24RE Series Recess Gauge Z60480

Used to check the size and position of the implant bone recess and electrode exit excavation.

CI24RE Series Implant Template Z33019

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

CI24RE Series Array Exit Marking Template Z33017

Used to check the bone recess size, select the implant's final position by rotating the instrument in the bone recess, and mark the width and exit position of the channel for the intracochlear and extracochlear electrodes.

Contour Electrode Claw Z33021

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

CI24RE Series 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.

CI24RE Series Non-Magnetic Plug	Z50100
	If the recipient requires multiple MRI examinations on the head, a non-magnetic plug is used to replace the implant magnet. The non-magnetic plug is not intended for use unless required for multiple MRIs. If only a single MRI is required the magnet recess can remain empty. For more information see *MRI safety information* on page 27.

CI24RE Series Sterile Replacement Magnet	Z50101
	Used to replace a non-magnetic plug or fill an empty magnet recess after MRI examinations are complete. For more information see *MRI safety information* on page 27.

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***.

Non-sterile

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

Warning

Single-use items.

CI24RE Series Non-Sterile Silicone Implant Template Z33020

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

Warning

Do not sterilise. Do not use in the sterile field.

Spacer for Intraoperative Testing Z33012

When the processor coil is placed directly over the implant coil, use the spacer to check there is at least 2 mm between the coils.

Caution

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

Surgical Procedure

General surgical issues

Meningitis is a known risk of inner ear surgery. Candidates should be appropriately counselled of this risk and the vaccination status against organisms that cause meningitis. Broad-spectrum antibiotic coverage should be determined by the surgeon, to be consistent with best practice.

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. Typical separation is at least 10 mm.
2. Ensure the incision is large enough to accommodate the implant.
3. Prior to incision, the incision line may be infiltrated with 1 % Lidocaine with 1:100 000 or 1:200 000 adrenaline/epinephrine unless contraindicated.

2. Incision

Warning

If the patient has an implant in the other ear, monopolar electrosurgical instruments must not be used (bipolar electrosurgical instruments may be used).

1. Make the incision down to the avascular plane of the periosteum and temporalis fascia, and form a flap (a monopolar cutting current may be used). Stabilise the flap using retraction as necessary.
2. Create an anteriorly-based large palva flap.
3. Elevate a sub periosteal pocket for the receiver/stimulator. Ensure it is of adequate size by placing the receiver/stimulator template into the pocket.
4. Elevate a separate, sub periosteal pocket against the bone under the temporalis muscle for the extracochlear electrode ball between the skull and the periosteum.

3. Mastoidectomy and well

The mastoidectomy is described next. Some surgeons prefer to drill the well first.

The mastoidectomy

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

The well

1. Mark the well using the circular Bone Recess Template and/or the Implant Recess Template.
2. Drill the well bed. The round drill bed allows for some rotation of the receiver/stimulator, to achieve optimal placement.
3. Use the Bone Recess Template to check the well's final dimensions.
4. Place the Array Exit Marking Template in the well and rotate it to the optimum position.
5. Mark the exit of the electrode array.
6. Drill a channel to connect the well and the mastoid cavity. The channel will help to protect the electrode array against trauma.
7. Use the Recess Checking Gauge to check the position of the array exit.

4. Facial recess

1. Open the facial recess ensuring it gives as much visibility and access as possible. Opening up the facial recess fully and widely is the key to ensuring ease of placing the cochlear electrode. When done correctly, the recess allows easy access and the correct angles of insertion. The horizontal canal and short process of the incus should be clearly visualised.
2. Identify the facial nerve, but do not expose it. The facial nerve should be identified and bone removed anterior to it and anterior/inferiorly and anterior/medially. In addition, the bone lateral to it should be removed as well, coupled with a thin exterior auditory canal.
3. Identify the chorda tympani nerve.

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

   The view of the round window membrane is normally obstructed by a bony overhang of the lateral margin of the round window niche. In addition, a false membrane often covers the true membrane.

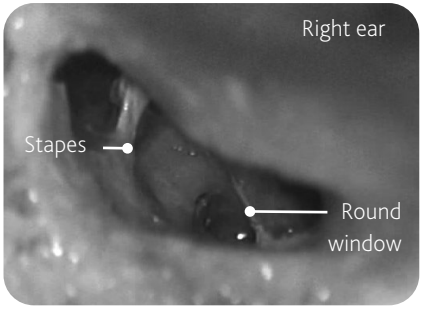


Figure 3: Pre removal of the bony overhang on the lateral rim of the round window

4. Remove the bony overhang using a 1.0 mm or a 1.5 mm diamond burr. Once the bone has been removed, the posterior portion of the middle ear, including the stapedius tendon, promontory and round window niche (RWN), should be clearly visualised.

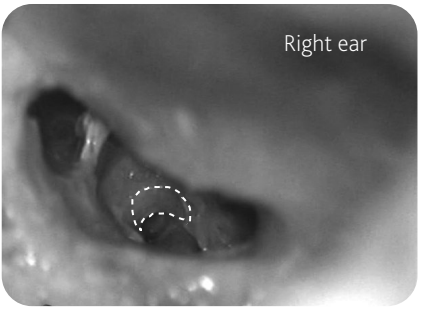


Figure 4: Post removal of the bony overhang on the lateral rim of the round window

5. Preparing the round window or cochleostomy

The Hybrid L24 implant electrode is compatible with both the round window (method 1) and traditional cochleostomy (method 2) approaches. This section describes the preparation of the site for both approaches. See later section for details on inserting the electrode array.

Note

Do not actually open the round window or cochleostomy until ready to insert the electrode.

Method 1 — 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.

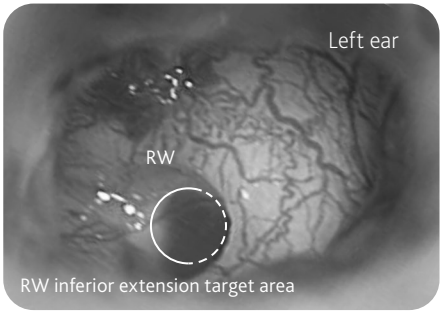


Figure 5: Round window target area

2. Remove the false membrane.
3. Immediately prior to inserting the electrode, a straight incision is made inferiorly in the round window from anterior to posterior.

Note

The diameter of the incision must be at least equal to the diameter of the electrode at the proximal end i.e. 0.6 mm diameter.

Method 2 — 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. It may be necessary to 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 diameter 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. 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.

   Drilling too far anteriorly or superiorly will result in the endosteum appearing white and the scala media or vestibuli may be entered. Drilling too far inferiorly will miss the cochlea entirely and a hypotympanic air cell may be entered, leading to incorrect electrode placement.

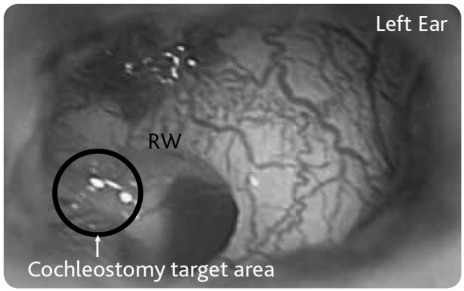


Figure 6: Cochleostomy target area

3. Drill sufficient bone with the 1.4 mm or 1.0 mm diameter diamond burr to expose at least 0.65–0.75 mm of endosteum. A 0.5 mm diameter diamond burr or a small foot plate hook (0.2 mm diameter) may be used to remove the final layer of bone.

⚠ Caution

A cochleostomy size of 0.6–0.7 mm is preferred. This size accommodates the diameter of the electrode adjacent to the stopper. A cochleostomy size greater than 1.2 mm may result in the unwanted insertion of the stopper into the cochlea.

The following should be performed immediately prior to insertion of the electrode:

1. Open the endosteum with a hook or needle.
2. Using stapes footplate instruments, remove any sharp edge of bone which might snag the electrode.

⚠ Caution

Do not suction the perilymph.

6. Inspecting the implant and electrodes

1. Remove the implant's outer packaging.
2. Break the seal on the outer tray, and without touching the device, confirm the inner packaging is not damaged, and that exposure to ethylene oxide processing is indicated.
3. Remove the sterile tray and confirm the implant is not damaged.
4. Lift the implant from the sterile packaging tray.

Note

Leave the protective tube on the array until just prior to insertion.

Caution

Monopolar electrosurgical instruments must not be used on the neck and head of a cochlear implant patient from this point. Bipolar electrosurgical instruments may be used; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm from the extracochlear electrodes.

7. Securing the device

Place the pedestal of the receiver/stimulator in the well, and place the electrode lead in the centre of the channel.

Caution

If rotating the implant in its bed, take care not to pinch the electrode lead between the edge of the bone channel and the pedestal.

If desired, secure the package with a suture using a non-absorbable synthetic material.

Caution

Do not suture directly over the magnet in case the magnet requires removal at a later date.

8. Securing the extracochlear electrode

Carefully place the extracochlear electrode against the bone under the temporalis muscle, minimising mechanical stress on the electrode lead. Do not place it in the temporalis muscle.

9. Inserting the electrode array

The forceps should be used to slowly insert the electrode array into the round window or cochleostomy, holding the electrode by the handle.

Note

- Use minimal force and insert the electrode slowly. A slow insertion reduces the risk of intracochlear trauma and allows displacement of the perilymph.
- Do not suction the perilymph from within, or near, the round window or cochleostomy.

1. Carefully remove the protective tube from the electrode array. Do not squeeze or stretch the array.
2. Holding the electrode by the handle, guide the tip toward the cochleostomy or round window ensuring that the half-band electrodes remain oriented toward the modiolus. The handle can be used to identify electrode orientation, as it is located on the opposite side of the electrode array. Advance the electrode slowly so that the first few electrodes are inserted.
3. Using the handle to maintain orientation, continue slowly inserting the electrode up to the white silicone stopper.
4. Stabilise the lead to prevent movement of the electrode array in the cochlea.

10. Securing and sealing the intracochlear electrode array

Caution

Immediately after electrode insertion and before arranging the excess proximal electrode lead in the mastoid cavity, it is important to immobilise the electrode by continuously holding it by the handle. Movement of the excess lead could result in the electrode twisting and potentially damaging structures, or possibly freeing itself from the cochlea.

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

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

Coil the excess redundant proximal electrode lead inside the mastoid cavity under the bony overhangs.

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

11. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed. Put the transmitting coil in a sterile sleeve, replace the flap and place the coil on top of the implant.

Note

The implant transmitting range is 2–10 mm. The implant may not function properly if the coil is directly on top of the receiver/stimulator.

12. Closure

The facial recess may be packed with soft tissue. Suture the palva flap over the proximal portion of the intracochlear electrode lead. Close the wound in layers. Drainage is not recommended. Apply a large mastoid dressing.

MRI safety information

The Cochlear Nucleus Hybrid L24 (CI24REH) implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

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

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

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

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

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

Removing the magnet

Caution

- Take care when removing or inserting the magnet or non-magnetic plug, so as not to damage the implant silicone. Exerting minimal force, always use a blunt instrument – such as an elevator – to lift the lip of the silicone elastomer recess. Minimise the pressure applied to the antenna of the implant.
- Magnets for the Cochlear Nucleus CI24RE Series implants are a different size to magnets for the Cochlear Nucleus CI500 Series implants. Ensure that the correct magnet is used.
- Non-magnetic plugs for the Cochlear Nucleus CI24RE Series implants are a different size to non-magnetic plugs for the Cochlear Nucleus CI500 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 prior to 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 star symbol (denoting polarity) facing up. See magnet images in ***Replacing the magnet*** on page 33. 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 33

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.

   ⚠ Caution

   - Do not use monopolar electrosurgical instruments.
   - Keep bipolar electrosurgical instruments at least 1 cm away from the extracochlear electrodes.

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 exam or multiple exams 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 30) and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing.

   The recess may remain empty with sterility maintained for a period of up to four hours.
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 33.

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 gwoing 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 30) 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 7: CI24RE Series non-magnetic plug

Caution

Non-magnetic plugs for CI24RE Series implants are a different size to non-magnetic plugs for CI500 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 33.

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 30) 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 star symbol (denoting polarity) facing up, as shown below.

Figure 8: CI24RE Series magnet facing upwards

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

Caution

Magnets for CI24RE Series implants are a different size to magnets for CI500 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.

General Information

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. Remove sutures on approximately the 10th day.

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).

Explantation

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

- Contact Cochlear to order a Retrieved Device Kit (Z25017). The kit must be used to transport the explanted device to Cochlear.
- Before explanting the device, examine it for any defects, and note these on the form provided with the kit.

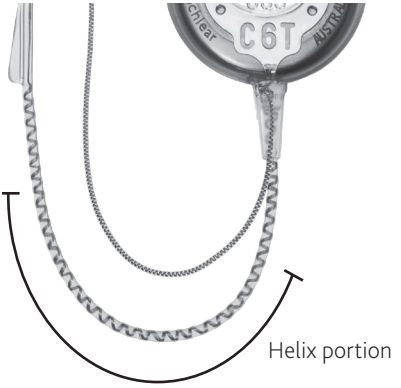


Figure 9: Helix portion of electrode lead

- Try to keep the explanted device intact and undamaged.
- Cut the intracochlear electrode lead if this will make it easier to remove the device without damaging it. The cut should be in the helix portion of the electrode lead.
- If the extracochlear electrode (ball) is difficult to remove, cut the extracochlear lead and leave the ball in place.
- If the intracochlear electrode array is removed from the cochlea, return it in the kit, even if it is damaged.

- If removal would cause excessive trauma, leave the distal end of the extracochlear electrode lead (with the ball electrode) in place.
- Return the kit containing the explanted device to Cochlear.

Problem reporting

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.

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 her/him. 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.

Registering the implant

Registration form

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

Patient Implant Card and Important Information document

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

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

Implant specifications for the Cochlear Nucleus Hybrid L24 cochlear implant

Electrodes

- 22 half-banded platinum electrodes, moulded with a silicone elastomer carrier, located towards the distal end of a 16 mm active array (tip to stopper).
- Proximal diameter of 0.55 x 0.4 mm tapering to a distal diameter of 0.35 x 0.25 mm.
- Two extracochlear electrodes: one platinum plate attached to the receiver/stimulator package, and a separate 1.5 mm (typical) diameter ball electrode on an 80 mm lead.
- A white silicone stopper limits intracochlear placement to the desired depth.

Receiver/stimulator

- Hermetically sealed titanium case
- Case dimensions: 25 mm x 19.3 mm x 4.9 mm
- Coil dimensions: 30.6 mm diameter x 6.9 mm thick
- Weight 9.5 g (including electrode array).

Operating characteristics

- Power and data received by a 5 MHz inductive link from the sound processor headset coil
- Delivers biphasic current pulses
- Delivers monopolar, bipolar or common ground stimulation
- Delivers stimulus amplitudes from 0 to 1.75 mA
- Delivers stimulus duration from 9.6 µs to 400 µs per phase.

Symbols used on implant packaging

The following symbols may appear on your implant packaging:

Fragile, handle with care

Do not use if package is damaged

Consult instructions for use

Refer to instruction manual

Specific warnings or precautions associated with the device, which are not otherwise found on the label

Do not re-use

Do not resterilise

Date of manufacture

Manufacturer

Use-by date

Temperature limits

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

Hear now. And always

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