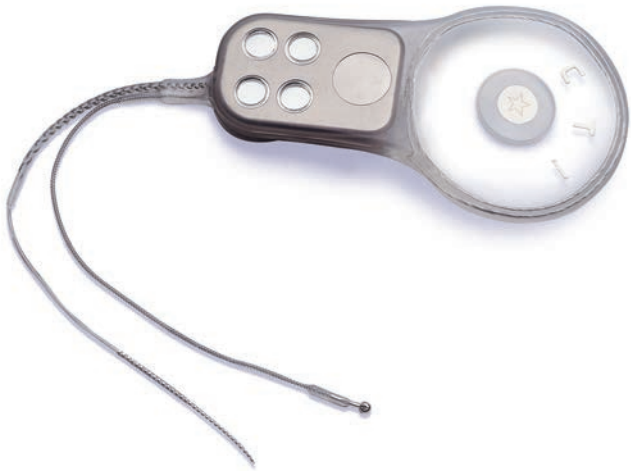
Nucleus® 24
CI24M
Surgeon's Guide



Hear now. And always Cochlear™

Contents

Introduction

About This Guide

This guide explains the general surgical procedure for implanting the Nucleus® 24 cochlear implant CI24M. It also provides important information on post-operative patient management. All personnel responsible for cochlear implantation and patient follow up should be familiar with the contents of this manual.

Instructions for installing the programming system and programming the Nucleus 24 system are found in the Installation Guide and the Programming Guide. These documents are packed with the Clinical Programming System and software products.

The implant centre is responsible for ensuring that the cochlear implant registration form is completed and returned to Cochlear.

The information in this manual is believed to be true and correct in every detail at the indicated date of publication. However, specifications are subject to change without notice.

Please read the Package Insert and Warnings & Precautions Leaflet included in each cochlear implant document package. They contain important information on MRI, indications, contraindications, adverse effects, warnings and precautions.

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 him/her. The Cochlear terms and conditions of warranty should therefore be given to the patient before implantation of the cochlear implant.

The Nucleus Cochlear Implant System

The Nucleus 24 cochlear implant system is intended to restore a level of auditory sensation via the electrical stimulation of the auditory nerve in adults and children.

The system consists of the CI24M cochlear implant which can be

used with a body worn speech processor or a behind the ear speech processor.

The CI24M cochlear implant consists of a receiver/stimulator which receives and decodes the electrical signal and an electrode array which delivers the signal to the cochlea. It has 22 intracochlear electrodes, one ground electrode on the electronics package, and the other ground electrode on a lead.

Radiopaque Lettering Code

Each cochlear implant has a radiopaque label to enable the device to be identified by X-ray after implantation. The label consists of three platinum letters to identify: the manufacturer, the device model number, and the year of manufacture.

The letter in the left position indicates the manufacturer of the implant. "C" indicates "Cochlear".

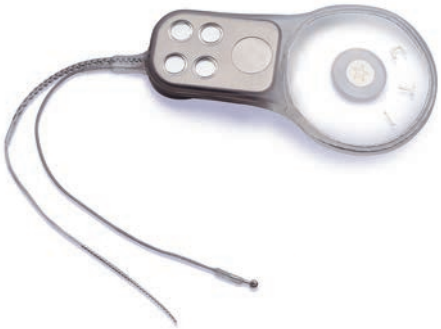
The letter in the middle position indicates the implant model. T indicates Nucleus 24.

The letter in the right position indicates the year of manufacture, up to and including 2004. Implants manufactured after 2004 will show 'T' in this position, regardless of the year of manufacture.

Letter	A	B	C	F	G	H	I
Year	1992	1993	1994	1995	1996	1997	1998
Letter	J	K	L	N	S	T	
Year	1999	2000	2001	2002	2003	2004 and later	

Year of manufacture

The radiopaque lettering on this implant shows that it is: made by Cochlear (C), model CI24M (T), manufactured in 1998 (I).



Nucleus 24 cochlear implant

Surgical Kit

The CI24M Surgical Kit (Z30017) contains the following tools.

Implant template

This template is non-sterilizable.

This is a silicone elastomer template for determining the optimum implant position and tracing it onto the skin prior to incision. The template is available for re-order in a separate 5 pack.

> **Note:**
>
> The silicone elastomer implant template must only be used before the sterile field is established. This is a single-use item that should not be sterilised.

BTE template

This template is resterilizable.

The BTE template is used to ensure that the implant is positioned with sufficient space for a behind the ear speech processor, which the patient may choose to use in conjunction with the implant. The template is made from stainless steel and, once sterilized, can be used in the sterile field.

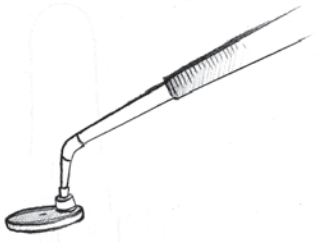
Outline template

This template is resterilizable

The outline template is used to measure the correct size of the well before placing the implant on the skull. The upper surface is marked to indicate the exit position and width of the electrode array and extra-cochlear lead. This instrument is made from stainless steel.

Recess template

This template is resterilizable.



This is a round, stainless steel template with handle, used for marking the well on the skull.

Electrode claw

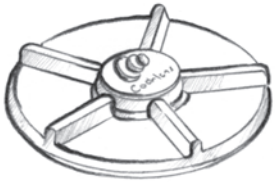
This claw is resterilizable.

The electrode claw is used to insert the electrode into the cochlea. This instrument is made from stainless steel.

Other Tools

Spacer for intraoperative testing

The spacer is non-sterilizable and requires a sterile sheath for use.



Used to ensure there is at least 2 mm distance between the transmitting coil and the implant antenna when the coil is placed directly over the antenna.

Available as a single item.

Surgical Procedure

General Surgical Issues

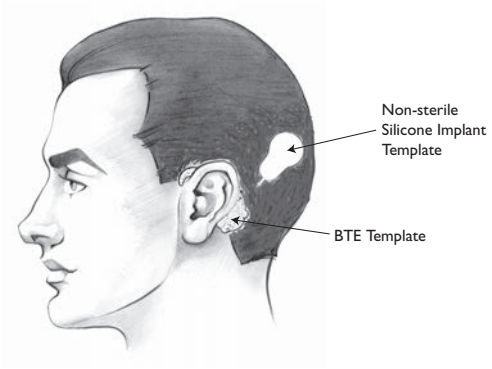
The routine use of a facial nerve monitor is advised, and is particularly important for cases of congenital temporal bone anomalies, revision surgeries, and other cases in which the facial nerve may be at greater risk.

Broad-spectrum antibiotic coverage for the operation is important. Coverage should be determined by the surgeon, to be consistent with best practice.

1. Pre-Incision – Non-Sterile Field

Place the non-sterile silicone elastomer implant template on the skin so that the antero-inferior edge is at least 10 mm behind the edge of the auricle and above the cantho-meatal line. Angle the template 30 to 45 degrees postero-superiorly to lie on a flat portion of the skull, and mark its position on the scalp.

Use the BTE template in conjunction with the silicone elastomer implant template to ensure there will be no interference between the coil and an ear level speech processor, making sure the speech processor will not rest on the receiver/stimulator.



Placing the implant

Mark the incision with a marking pen, and allow at least 15 mm between the receiver/stimulator and the incision.

The centre of the proposed well for the implant bed is marked with a drop of methylene blue deposited on bone by inserting an 18 gauge needle through the skin.

2. Incision

Make an incision and form a flap. The incision must be large enough to accommodate the receiver/stimulator, and there should be at least 15 mm between the receiver/stimulator and the incision. The flap may be inferiorly- or anteriorly-based, but must allow the surgeon to secure the implant to bone.

Make the incision down to the avascular plane of the periosteum and temporalis fascia. Stabilize the flap using retraction as necessary.

Check the position of the implant with the sterile stainless steel outline template from the surgical kit. Next, incise the underlying periosteum and lower portion of the temporalis fascia muscle creating an anteriorly-based large palva flap.

Elevate a large periosteal pocket for the antenna.

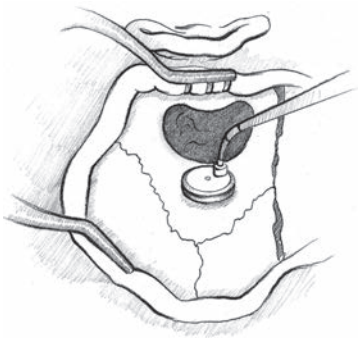
Elevate a periosteal pocket deep to the temporalis muscle. This will allow the placement of the extracochlear ball electrode between the skull and the periosteum. Avoid placing the extracochlear ball electrode in the temporalis muscle.

3. Mastoidectomy and Well

It is preferable to perform the mastoidectomy next, although some surgeons prefer to drill the well first.

The position of the well is verified by the blue dye dot on the bone. Create an adequate mastoidectomy cavity, allowing an overhang both superiorly and posteriorly in order to accommodate the redundant proximal electrode.

It is recommended that in children, a complete mastoidectomy be performed.



Using the recess template

Drill a circular drill bed using the recess template as a guide. Although the receiver/stimulator package is oval shaped, the recess template is round. The resulting drill bed is round to allow for rotation of the receiver/stimulator, should it be required to achieve optimal placement.

Drill a channel connecting the well and the cavity, so that the proximal intracochlear electrode array is guided in the direction of the facial recess. It is preferred that the receiver/stimulator not extend over the edge of the mastoid cavity.

4. Tie-Down Holes

Determine the longitudinal axis for the receiver/stimulator and then mark tie-down holes above and below the anterior portion of the receiver stimulator to ensure that the implant is secure. Drill these holes with a 2 mm diamond burr.

For additional support, posterior tie-down holes may be drilled, or the antenna portion can be placed under a pericranium/temporalis pocket.

5. Facial Recess

Open the facial recess in the usual fashion. The horizontal canal and short process of the incus should be clearly visualised. Identify the facial nerve, but do not expose it.

The chorda tympani nerve can almost always be preserved, but damage may occur when excessive bone is left on the anterior surface

of the facial nerve.

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

6. Cochleostomy

Visualize the stapes to confirm the site of the round window, and visualize the round window membrane. The round window niche is approximately 2 mm inferior and slightly posterior to the oval window and stapes. 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 visualize the round window membrane itself.

Perform a cochleostomy into the scala tympani by drilling anteroinferiorly to the round window niche. The cochleostomy may be separate to, or may incorporate the round window membrane. If a separate cochleostomy is created, care must be taken to site the cochleostomy anteroinferior rather than anterior to the round window. Drilling anteriorly on the promontory will enter the scala media or vestibuli. Drilling too far inferiorly will miss the cochlea entirely and may enter a hypotympanic aircell leading to incorrect electrode placement.

Drill sufficient bone with the 1 or 1.4 mm diamond burr until a 1 mm spot of endosteum is exposed. Care should be taken to prevent bone dust and blood from entering the cochleostomy.

Using stapes footplate instruments, open the endosteum and ensure that the cochleostomy is at least 1 mm diameter to admit the electrode array. If the cochleostomy incorporates the round window membrane, the posteroinferior edge of the cochleostomy may need to be drilled to ensure the electrodes do not catch on the bony ridge.

Caution:

Once the implant is in contact with the patient, monopolar cautery must not be used. Bipolar electrosurgical instruments may be used if the cautery electrodes are kept more than 1cm from the extracochlear electrodes.

Open the implant package, remove the device, and check for any evidence of damage.

Grasp the receiver/stimulator in the non-dominant hand and remove the protective tube from the electrode array. Guide the tip of the electrode array toward the cochleostomy using the claw or side of a fine suction tip in the other hand. By advancing both hands, the first few electrodes can usually be inserted. Use the claw to stroke the array into the scala tympani, using no force, and attempting to insert only a few electrodes at a time.

If obstruction is encountered, back out one or two rings, rotate the implant toward the modiolus (clockwise for the left ear, counter-clockwise for the right) and attempt further insertion. Do not use force and do not allow the electrode array to kink.

Remember that it is not necessary to insert all rings, and that a partial insertion is better than a damaged array.

Inserting the electrode array

7. Device and Electrode Array Fixation

It is important that the electrode array is secured at two points to limit the risk of migration or breaking the seal between the electrode array and the tissue packing at the cochleostomy.

The electrode array should be secured in close proximity to its exit from the cochleostomy. The method of fixation will depend on surgical access and the surgeon's discretion and may include wedging the array (the incus bridge) or the use of specifically designed surgical clips.

Place the pedestal of the receiver/stimulator in the well, and rotate it to the proper angle.

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.

Secure the package with a single mattress suture, using a non-absorbable material. Move the knot to the edge of the implant. Tie the antenna portion, or place it under a pericranial/temporalis pocket.

Caution:

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

Place the extracochlear ball electrode in the periosteal pocket under the temporalis muscle.

Note:

The extracochlear ball electrode must not be placed in the temporalis muscle.

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

8. Intraoperative Measurements

Intraoperative measurements via telemetry may be performed at this time. When performing telemetry measurements, use the Intraoperative Spacer between the implant and the transmitting coil to ensure that there is adequate distance between the CI24M and the external transmitting coil for testing.

Cover the coil and the spacer with a sterile sheath.

Note:

The transmitting range for the CI24M is 2 - 10 mm; the CI24M will not function properly if the transmitting coil is placed directly on top of the receiver/stimulator.

9. Closure

Caution:

Once the implant is in contact with the patient, monopolar cautery must not be used. Bipolar electrosurgical instruments may be used if the cautery electrodes are kept more than 1cm from the extracochlear electrodes.

While the patient is still under anaesthesia and in the sterile field, a single transorbital X-ray may be obtained in order to assure the proper electrode placement.

Pack the facial recess with soft tissue. Suture the palva flap over the proximal portion of the intracochlear electrode. Close the wound in layers.

Drainage is usually not necessary. Apply a large mastoid dressing.

Post-operative Patient Management

Wound Care

The patient should be monitored as for all procedures involving general anaesthesia. The pressure dressing should be kept on for one day and then the wound inspected and another dressing applied for five days. The sutures should be removed at about the tenth day.

Patient Follow-up

The initial fitting procedure should be scheduled three to four weeks after the operation. Typically, several sessions are required before the most suitable setting is achieved. Children are more difficult to program than adults, and the implant team will generally involve other professionals such as teachers in the habilitation program.

The fitting of the speech processor should be checked at three months, six months and one year postoperatively, and from then on at yearly intervals (or more frequently if required by the condition of the patient). Further training should be available to the patient if needed. During the follow-up checks, psychophysical and telemetry measurements should be undertaken, and closed-set and open-set speech recognition ability should be evaluated.

Problem Reporting

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

Magnetic Resonance Imaging

The CI24M cochlear implant is designed to withstand Magnetic Resonance Imaging (MRI) at field strengths described in the Warnings and Precautions leaflet. At some field strengths, the magnet must be removed surgically before the patient undergoes an MRI procedure.

Please read the MRI section of the Warnings and Precautions leaflet before following the instructions below.

Removing the Magnet before Implantation

If a new recipient has a known condition that requires MRI examinations, it may be appropriate to replace the magnet with a non-magnetic titanium plug before the device is implanted.

The replacement procedure should take place under sterile conditions as follows:

1. Remove the cochlear implant from its sterile packaging and place it on a flat and stable surface, with the star symbol on the magnet facing up. Do not remove the protective tube from the electrode array.
2. Using an elevator or similar instrument, lift the tip of the silicone elastomer recess around the magnet and remove the magnet from the implant. When removing the magnet, minimize the pressure applied to the antenna of the implant.
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.
4. The cochlear implant is now ready for implantation.

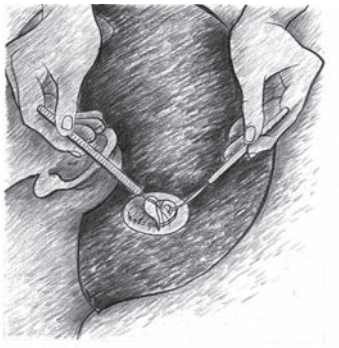
Replace the magnet when there is no further need for MRI examinations, following the procedures below.

To wear an external transmitter coil while the implant has no magnet in place, the patient must wear a retainer disc.

Removing the Magnet after Implantation

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

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



Removing the Magnet

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

Single MRI

For a single MRI examination:

1. Make a small incision and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing, without closing the wound.

   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, insert a sterile replacement magnet with the star symbol (denoting polarity) facing up.
5. Use an elevator to lift the lip of the recess and position the magnet.
6. Close the wound in layers.

Long Term MRI

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

The patient must wear a retainer disc to hold their external transmitter coil in place when the magnet has been removed.

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

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

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

1. Make a small incision and remove the magnet.
2. Lift the lip of the recess using an elevator and press the non-magnetic plug into position, being careful not to exert undue pressure on the implant.
3. Close the wound in layers.

When MRI is no longer a regular necessity:

1. Make a small incision exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a sterile replacement magnet with the star symbol (denoting polarity) facing up. Use an elevator to lift the lip of the recess and position the magnet.
4. Close the wound in layers.

General Information

CI24M Specifications

Electrodes

- Number of pure platinum rings: 32 (22 active electrodes and 10 inactive stiffening rings) moulded with a silicone elastomer carrier.
- 22 platinum electrodes spaced over a 17 mm active array. Diameter of intra-cochlear section: 0.6 mm basal and 0.4 mm apical.
- The 10 stiffening rings are inactive and help stiffen the carrier. This assists the surgeon inserting the array into the scala tympani.
- The band-shaped electrodes may be rotated during insertion.
- Two extracochlear electrodes; 4 platinum plates attached to the receiver/stimulator package and a separate 1.5 mm (typical) diameter ball electrode on a 90 mm lead.

Receiver/stimulator

- has an hermetically sealed titanium case
- case dimensions: 27 x 18 x 6.4 mm (typical)
- coil dimensions: 33 mm diameter x 3.5 mm thick (typical)
- weight 9.5 g

Operating characteristics

- power received by a 5 MHz inductive link from the headset coil
- delivers biphasic current pulses
- 5 MHz carrier frequency
- delivers monopolar, bipolar or common ground stimulation
- delivers stimulus amplitudes from 10 μA to 1.75 mA nominal
- delivers stimulus duration from 25 μs to 400 μs

Cochlear Implant Registration

In accordance with international practice and regulatory legislation, a cochlear implant registration form is packed with each Nucleus cochlear implant. The purpose of this form is to maintain traceability of all cochlear implants and secure warranty rights. It also allows the centre involved in the evaluation of the implant to quickly gain access to pertinent data from the manufacturer.

A Patient Identification Card is also provided and the patient should carry it with him/her at all times.

It is the responsibility of the implant centre to ensure that both the Registration Form and the Patient Identification Card are completed correctly and that a complete copy of the Implant Registration Form is returned to the manufacturer at the address shown on the form within 30 days of implantation.

This information will be collected in accordance with local law, the legal requirements of the Swiss data protection law of 01.07.93 and in accordance with the European guidelines on data protection.

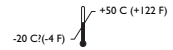
Certification and applied standards

The Nucleus 24 cochlear implant systems fulfil the essential requirements listed in Annex 1 of the EC directive 90/385/EEC on Active Implantable Medical Devices as last amended by EC Directive 93/68/EEC. They were approved for CE-Mark according to Annex 2 by Notified Body 0197 in 1995/1996 and 2001.

CE 0197

International Labelling Symbols

The symbols below are used on implant packaging.

Symbol	Meaning
	Fragile
	See instructions for use
	Do not reuse
 2002-05-30	Date of manufacture
 2004-05-30	Use by date
	Temperature limit
	Humidity Limit
STERILE | EO	Sterile and Method of sterilisation (EO = Ethylene oxide)
LOT 12345	Lot number or Batch number
REF 12345	Reference number or Part number
SN 12345	Serial Number
	CE Registration Mark

Cochlear Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove NSW 2066, Australia Tel: 61 2 9428 6555 Fax: 61 2 9428 6352
Cochlear Americas 400 Inverness Parkway, Suite 400, Englewood CO 80112, USA Tel: 1 303 790 9010 Fax: 1 303 792 9025
Cochlear Europe Ltd 22-24 Worple Road, Wimbledon, London SW19 4DD, United Kingdom Tel: 44 20 8879 4900 Fax: 44 20 8946 9066
Cochlear AG Margarethenstrasse 47, CH - 4053 Basel, Switzerland Tel: 41 61 205 0404 Fax: 41 61 205 0405
Cochlear GmbH Karl-Wiechert-Allee 76A, D-30625 Hannover, Germany Tel: 49 511 542 770 Fax: 49 511 542 7770
Nihon Cochlear Co Ltd Ochanomizu-Motomachi Bldg, 2-3-7 Hongo, Bunkyo-Ku, Tokyo 113-0033, Japan Tel: 81 3 3817 0241 Fax: 81 3 3817 0245
Cochlear (HK) Ltd 21F Shun Ho Tower, 24-30 Ice House Street, Central, Hong Kong Tel: 852 2530 5773 Fax: 852 2530 5183
www.cochlear.com

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