



# **Cochlear™**

# **Non-Magnetic Plugs and Replacement Magnets**

## **User Guide**

United States of America and Canada

For Professionals



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# About this guide

This guide is for healthcare professionals using:

- Cochlear™ CI24RE Series Sterile Non-Magnetic Plug
- Cochlear CI500 Series Sterile Non-Magnetic Plug
- Cochlear Sterile Non-Magnetic Plug
- Cochlear CI24RE Series Sterile Replacement Magnet
- Cochlear CI500 Series Sterile Replacement Magnet
- Cochlear Sterile Replacement Magnet.



## Note

- Non-magnetic plugs and replacement magnets are single-use, sterile surgical accessories.
- Refer to the relevant sections for cautions and warnings relating to the use of these devices.

## Symbols used in this document



**Note:** Important information or advice.

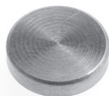


**Caution (no harm):** Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.



**Warning (harmful):** Potential safety hazards and serious adverse reactions. Could cause harm to person.

# Non-magnetic plugs and replacement magnets



Cochlear CI24RE Series Sterile Non-Magnetic Plug (Z50100)



Cochlear CI500 Series Sterile Non-Magnetic Plug (Z146624)



Cochlear Sterile Non-Magnetic Plug (P1620901)



Cochlear CI24RE Series Sterile Replacement Magnet (Z50101)



Cochlear CI500 Series Sterile Replacement Magnet (Z179608)



**Note**

Some CI500 Series implant recipients may have a magnet with a Cochlear logo.



Cochlear Sterile Replacement Magnet (P1620873)

# Indications

## Non-magnetic plug

The non-magnetic plug is indicated for use when MRI scans are conducted with a hearing implant recipient, when the implant magnet is removed. It helps to minimise the growth of fibrous tissue and prevent debris entering the implant recess. It is indicated for use when the implant magnet is removed for MRI scans performed over multiple days.

### **Cochlear CI24RE Series Sterile Non-Magnetic Plug**

The Cochlear CI24RE Series Sterile Non-Magnetic Plug is indicated for a recipient with the following compatible Cochlear Nucleus® hearing implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)
- CI24R and CI24M Series Implants: CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M, CI11+11+2M
- CI22M with removable magnet.

## **Cochlear CI500 Series Sterile Non-Magnetic Plug**

The Cochlear CI500 Series Sterile Non-Magnetic Plug is indicated for a recipient with the following compatible Cochlear Nucleus hearing implants:

- CI500 Series Implants: CI512, CI522, CI532, CI532P, ABI541.

## **Cochlear Sterile Non-Magnetic Plug**

The Cochlear Sterile Non-Magnetic plug is indicated for Cochlear Osia® OSI200 Implant recipients requiring multiple MRI examinations.

## **Replacement magnet**

The replacement magnet is indicated for use when the hearing implant requires a new magnet due to removal of the original magnet, to restore the medical functionality of the implant.

## **Cochlear CI24RE Series Sterile Replacement Magnet**

The Cochlear CI24RE Series Sterile Replacement Magnet is indicated for a recipient with the following compatible Cochlear Nucleus hearing implants:

- CI24RE Series Implants: CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)
- CI24R and CI24M Series Implants: CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M, CI11+11+2M
- CI22M with removable magnet.

### **Cochlear CI500 Series Sterile Replacement Magnet**

The Cochlear CI500 Series Sterile Replacement Magnet is indicated for a recipient with the following compatible Cochlear Nucleus hearing implants:

- CI500 Series Implants: CI512, CI522, CI532, CI532P, ABI541.

### **Cochlear Sterile Replacement Magnet**

The Cochlear Sterile Replacement Magnet is indicated for Cochlear Osia OSI200 Implant recipients requiring implant magnet replacement.

# Warnings

- To minimise the risk of infection or fibrous tissue growing into the implant recess, do not leave the magnet pocket empty for MRI examinations taking place over a period of time. When removing a magnet, replace with a non-magnetic plug.
- **Replacement magnets** contain a magnet, which should be kept away from neurostimulation devices (for example, deep brain stimulators) and magnetic ventricular shunts, as the magnet 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 the replacement magnet in place**, in any direction is less than 300 gauss.
- The non-magnetic plug and the replacement magnet are supplied separately in sterile packs. Both are single-use items.
- Do not resterilise.
- 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, for example, dropped or mishandled in theatre after removal from packaging.
- Before opening the sterile package, inspect it carefully.
- Return the device and packaging to Cochlear if:
  - the sterile pack containing the implant is ruptured or opened unintentionally
  - exposure to ethylene oxide processing is not indicated by a green dot on the sterile pack.
- For patient-specific warnings and cautions, the recipient should refer to the *Important Information* document.
- For additional warnings and cautions, refer to the Physician's Guide for the implant, or visit: [www.cochlear.com/warnings](http://www.cochlear.com/warnings).

# Opening the package

The non-magnetic plugs and the replacement magnets are packaged separately.

## Non-sterile field

1. Remove the cardboard box (outer packaging).
2. Visually inspect the outer tray and ensure that:
  - exposure to ethylene oxide processing is indicated by a green dot on the outer tray
  - the tray is not damaged.
3. Break the seal on the outer tray. Visually inspect the inner tray. Confirm that the inner tray is not damaged.

Notice that the inner tray containing the device is labelled Non-Magnetic Plug or Sterile Replacement Magnet.



### Warning

If the sterile pack is damaged or opened unintentionally, do not use the device.

## Sterile field

4. Break the seal on the inner tray.
5. Lift the device from the tray.
6. Confirm the device is not damaged.

# Removing the magnet and inserting a non-magnetic plug

If the implant magnet needs to be removed prior to an MRI examination, close coordination is required between the specialists to perform the implant magnet removal, MR scan, and subsequent implant magnet replacement.

For implant recipients requiring a single MRI examination or multiple MRI examinations over a period of time, the implant magnet can be removed and replaced with a sterile non-magnetic plug.

When there is no further need for MRI examinations, the non-magnetic plug is removed, and a replacement magnet is inserted.

For information on identifying a device without surgical intervention, refer to the *Cochlear Nucleus Implants MRI Guidelines* or *Cochlear Osia MRI Guidelines*.



## 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.
- Take care when inserting a non-magnetic plug. Non-magnetic plugs for the Cochlear Nucleus CI500 Series implants are a different size to non-magnetic plugs for the Cochlear Nucleus CI24RE Series implants. Ensure that the correct non-magnetic plug is used.



## Note

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

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

1. Make a small incision ensuring there is good access to the magnet.
2. Cut through any fibrous growth around the implant and expose the magnet.
3. Using an elevator or similar instrument, carefully lift the lip of the silicone elastomer recess and remove the magnet.  
If a retaining suture runs across the magnet, move the suture out of the way.
4. Remove the non-magnetic plug from its packaging.



**Figure 1:** Cochlear CI500 Series Sterile or Cochlear Sterile Non-Magnetic Plug



### Caution

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



### Warning

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

5. 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.
6. Close the wound in layers.

When there is no further need for MRI examinations, insert a replacement magnet as instructed in *Inserting a replacement magnet* on page 12.

# Inserting a replacement magnet



## Caution

Take care when inserting a replacement magnet. Replacement magnets for the Cochlear Nucleus CI500 Series and Cochlear Osia OSI200 implants are a different size to magnets for the Cochlear Nucleus CI24RE Series implants. Ensure that the correct replacement magnet is used.

When there is no further need for MRI examinations, remove the magnet in sterile conditions, using either general or local anaesthetic.

1. Under sterile conditions, make a small incision.
2. Remove the non-magnetic plug, using the procedure described in the previous section.



## Warning

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

3. Insert a new sterile replacement magnet, available from Cochlear, with the black ring or a star (denoting polarity) facing up, as shown below.



**Figure 2:** Cochlear CI500 Series Sterile or Cochlear Sterile Replacement Magnet with black ring facing upwards



**Figure 3:** CI24RE Series Sterile Replacement Magnet facing upwards

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



**Note**

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

5. Close the wound in layers.

For additional information about magnet removal, contact Cochlear.

# MRI safety information



The non-magnetic plugs and the replacement magnets are 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.

The replacement magnets are identical to the magnet assemblies originally incorporated into the implants with which they are compatible. Accordingly, the MR conditions of the implants incorporating replacement magnets are identical to the MR conditions of the implants with their original magnet.

Full MRI safety information is available:

- in the *Cochlear Nucleus Implants MRI Guidelines* or *Cochlear Osia MRI Guidelines*
- by visiting [www.cochlear.us/mri](http://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 (for example, 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.

# How the devices are supplied

The non-magnetic plugs and the replacement magnets are single-use items.

**Warning**

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

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

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

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

## Transport and handling

Non-magnetic plugs and replacement magnets 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 the devices inside their packaging at room temperature. Keep dry.

The product and its packaging have been designed to withstand storage temperatures from +1 °C (+34 °F) to +30 °C (+86 °F) and transient and seasonal excursions beyond this range.

# Materials and substances

The following materials are expected to be in direct contact with body tissue.

Item	Material
Cochlear CI500 Series Sterile Non-Magnetic Plug and Cochlear Sterile Non-Magnetic Plug	Titanium (grade 2)
Cochlear CI500 Series Sterile Replacement Magnet and Cochlear Sterile Replacement Magnet	Titanium (grade 2)
Cochlear CI24RE Sterile Non-Magnetic Plug	Titanium (grade 2)
Cochlear CI24RE Sterile Replacement Magnet	Titanium (grade 1)

In accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, the following materials present in the devices are considered carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, but are not expected to be in direct contact with body tissue:

Item	Material
Cochlear CI24RE Sterile Replacement Magnet	Cobalt

**Product component measurements**

<b>Item</b>	<b>Weight</b>	<b>Diameter</b>	<b>Thickness</b>
Cochlear CI500 Series Sterile Non-Magnetic Plug and Cochlear Sterile Non-Magnetic Plug	1.1 g	11.84 mm	2.2 mm
Cochlear CI500 Series Sterile Replacement Magnet and Cochlear Sterile Replacement Magnet	1.4 g	11.95 mm	2.2 mm
Cochlear CI24RE Sterile Non-Magnetic Plug	1.0 g	10.9 mm	2.5 mm
Cochlear CI24RE Sterile Replacement Magnet	1.6 g	10.9 mm	2.5 mm

# Disposal

Non-magnetic plugs and replacement magnets that have been in patient contact should be placed into the correct clinical waste container for disposal. Follow the legal provisions for your country and the hygiene instructions of your hospital or clinic.

Non-magnetic plugs and replacement magnets that have not been in patient contact can be disposed of as normal hospital or household waste, or in accordance with local regulations.

# Serious incidents

Whilst serious incidents in relation to medical devices are rare, it is acknowledged that incidents may happen. As an organisation, Cochlear recognises the potential for harm and will respond to any reported serious incident.

## What is a serious incident?

A 'serious incident' means any event that directly or indirectly has caused or could have caused an unexpected or unwanted event including:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat.

## Reporting a serious incident

There is no definitive list of events or incidents that constitute a serious incident, however all serious incidents should be reported to:

- your local Cochlear office  
[www.cochlear.com/intl/contact/global-offices](http://www.cochlear.com/intl/contact/global-offices)
- your National Regulator.

# Expected device lifetime

Cochlear Nucleus implants do not have a specified end of life date and are designed to remain operational for a period exceeding the warranty period of 10 years. Statistical analysis of historical reliability data including accelerated life testing results for Cochlear Nucleus Implants indicates the expected lifetime of the majority of devices is over 75 years.\*

However actual implant life may differ from this and can be related to the recipient's individual circumstances.














The Cochlear Osia OSI200 Implant does not have a specified end of life date and is designed to remain operational for a period exceeding the warranty period of 10 years. The actual device lifetime beyond 10 years will depend on a number of factors and may be related to the recipient's individual circumstances.











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\* This forward looking statement is based on a number of assumptions which may prove to be incorrect due to significant uncertainties, risks and contingencies, many of which are outside the control of, and/or are unknown to Cochlear Limited.

# Labelling symbols

The following symbols may appear on non-magnetic plugs or replacement magnets and/or packaging.

Symbol	Description
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Consult instructions for use
	Manufacturer
	Do not use if package is damaged and consult instructions for use
	Do not reuse
	Do not resterilise
	Authorised representative in the European Community/European Union
	Authorised representative in Switzerland
	Unique Device Identifier
	Medical Device
	Catalogue number
	Serial Number
	Batch code

Symbol	Description
	Date of manufacture
	CE registration mark with notified body number
	CE registration mark
	Caution: US law restricts this device to sale by, or on the order of, a physician
	Use-by date
	Sterile barrier system with protective packaging inside
	Keep dry
	Fragile
	Sterilised using ethylene oxide
	MR Conditional

# Trademark legal notice

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントゥア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, SoundBand, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.



# Hear now. And always

**AU** Cochlear Ltd (ABN 96 002 618 073)  
1 University Avenue, Macquarie University,  
NSW 2109, Australia  
Tel: +61 2 9428 6555

**ECREP DE** Cochlear Deutschland GmbH  
& Co. KG Mailänder Straße 4 a, 30539  
Hannover, Germany  
Tel: +49 511 542 770

**CHREP CH** Cochlear AG Peter Merian-Weg  
4, 4052 Basel, Switzerland  
Tel: +41 61 205 8204

**US** Cochlear Americas 10350 Park Meadows  
Drive, Lone Tree, CO 80124, USA  
Tel: +1 (800) 523 5798

**CA** Cochlear Canada Inc 2500-120 Adelaide  
Street West, Toronto, ON M5H 1T1, Canada  
Tel: +1 (800) 523 5798

**GB** Cochlear Europe Ltd 6 Dashwood Lang  
Road, Bourne Business Park, Addlestone,  
Surrey KT15 2HJ, United Kingdom  
Tel: +44 1932 26 3400

**BE** Cochlear Benelux NV  
Schaliënhoedreef 20 i, B-2800 Mechelen,  
Belgium  
Tel: +32 15 79 55 11

**FR** Cochlear France S.A.S. 135 Route de  
Saint-Simon, 31035 Toulouse, France  
Tel: +33 5 34 63 85 85 (International)  
or 0805 200 016 (National)

**IT** Cochlear Italia S.r.l. Via Trattati  
Comunitari Europei 1957-2007 n.17, 40127  
Bologna (BO), Italy  
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62

**SE** Cochlear Nordic AB Konstruktionsvägen  
14, 435 33 Mölnlycke, Sweden  
Tel: +46 31 335 14 61

[www.cochlear.com](http://www.cochlear.com)

**TR** Cochlear Tıbbi Cihazlar ve Sağlık  
Hizmetleri Ltd. Şti. Küçükbakkalköy Mah, Defne  
Sok, Büyükhanlı Plaza No:3 Kat:3 Daire: 9-10-  
11-12, 34750, Ataşehir, İstanbul, Türkiye  
Tel: +90 216 538 5900

**HK** Cochlear (HK) Limited Room 1404-1406,  
14/F, Leighton Centre, 77 Leighton Road,  
Causeway Bay, Hong Kong  
Tel: +852 2530 5773

**KR** Cochlear Korea Ltd 2nd Floor, Yongsan  
Centreville Asterium, 25, Hangang-daero 30 gil,  
Yongsan-gu, Seoul, Korea (04386)  
Tel: +82 2 533 4450

**CN** Cochlear Medical Device (Beijing) Co.,  
Ltd Unit 2608-2617, 26th Floor, No.9 Building,  
No.91 Jianguo Road, Chaoyang District, Beijing  
100022, P.R. China  
Tel: +86 10 5909 7800

**IN** Cochlear Medical Device Company  
India Pvt. Ltd. Ground Floor, Platina Building,  
Plot No C-59, G-Block, Bandra Kurla Complex,  
Bandra (E), Mumbai – 400 051, India  
Tel: +91 22 6112 1111

**JP** 株式会社日本コクレア(Nihon Cochlear  
Co Ltd) 〒113-0033 東京都文京区本郷2-3-7 お茶  
の水元町ビル  
Tel: +81 3 3817 0241

**AE** Cochlear Middle East FZ-LLC Dubai  
Healthcare City, Al Razi Building 64, Block  
A, Ground Floor, Offices IR1 and IR2, Dubai,  
United Arab Emirates  
Tel: +971 4 818 4400

**PA** Cochlear Latinoamérica S.A. International  
Business Park, Building 3835, Office 403,  
Panama Pacifico, Panama  
Tel: +507 830 6220

**NZ** Cochlear NZ Limited Level 4, Takapuna  
Towers, 19-21 Como St, Takapuna,  
Auckland 0622, New Zealand  
Tel: + 64 9 914 1983