

# Cochlear™ non-magnetic plugs & replacement magnets Important Information Booklet

Asia Pacific

*Hear now. And always*





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# About this document

This document applies to

- Cochlear™ CI500 Series Sterile Non-Magnetic Plugs,
- Cochlear Non-Magnetic Cassettes,
- Cochlear CI24RE Series Sterile Non-Magnetic Plugs,
- Cochlear Sterile Non-Magnetic Plugs,
- Cochlear CI500 Series Sterile Replacement Magnets,
- Cochlear Replacement Magnet Cassettes,
- Cochlear CI24RE Series Sterile Replacement Magnets and,
- Cochlear Sterile Replacement Magnets.

It is intended for cochlear implant recipients and their carers.

## Read this document carefully

This document contains information relating to the non-magnetic plugs, non-magnetic cassettes, replacement magnet cassettes and replacement magnets, including.

- device compatibility, and
- device specifications.

Please refer to your Nucleus Cochlear Implants Important Information document for warnings, cautions and essential advice that applies to cochlear implant systems. For additional warnings and precautions, refer to the Physician's Guide for the implant, or visit: [www.cochlear.com/warnings](http://www.cochlear.com/warnings)

## Symbols used in this document

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### Note

Important information or advice.

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### Caution (no harm)

Special care to be taken to ensure safety and effectiveness.  
Could cause damage to equipment.

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### Warning (harmful)

Potential safety hazards and serious adverse reactions.  
Could cause harm to person.

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# Non-magnetic plugs & replacement magnets



Cochlear CI500 Series Sterile Non-Magnetic Plug (Z146624)



Cochlear CI500 Series Sterile Replacement Magnet (Z179608)



Cochlear Non-Magnetic Cassette (P782484)



Cochlear Replacement Magnet Cassette (P782485)



**NOTE**

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



Cochlear CI24RE Series Non-Magnetic Plug (Z50100)



Cochlear CI24RE Series Replacement Magnet (Z50101)



Cochlear Sterile Non-Magnetic Plug (P1620901)



Cochlear Sterile Replacement Magnet (P1620873)

# Intended purpose

## Intended purpose

### Non-magnetic plug/Non-magnetic cassette

The non-magnetic plug/non-magnetic cassette is intended to be used temporarily in place of the magnet of a hearing implant after the implant magnet is removed.

### Replacement magnet/Replacement magnet cassette

The replacement magnet/replacement magnet cassette is intended to be used to replace the magnet of the hearing implant that has been removed to facilitate a medical procedure. The magnet enables an external coil to be retained in place and correctly aligned with the implant coil.

# 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 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 implants: CI500 Series Implants: CI512, CI522, CI532, ABI541.

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

The Cochlear Sterile Non-Magnetic Plug is indicated for a recipient with the following compatible cochlear implants: OSI200.

## Non-magnetic cassette

The non-magnetic cassette is indicated for use when MRI scans are conducted with a hearing implant recipient and the artefact from the magnet cassette may interfere with the MRI scan. 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 cassette is removed for MRI scans performed over multiple days.



The Cochlear Non-Magnetic Cassette is indicated for a recipient with the following compatible cochlear implants: CI600 Series Implants: CI612, CI622, CI624, CI632.

### 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 CI500 Series Sterile Replacement Magnet

The Cochlear CI500 Series Sterile Replacement Magnet is indicated for a recipient with the following compatible cochlear implants: CI500 Series Implants: CI512, CI522, CI532, ABI541

### Cochlear CI24RE Series Sterile Replacement Magnet

The Cochlear CI24RE Series Sterile Replacement Magnet is indicated for a recipient with the following compatible cochlear 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 Sterile Replacement Magnet

The Cochlear Sterile Replacement Magnet is indicated for a recipient with a compatible cochlear OSI200 implant.

### Replacement magnet cassette

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

The Cochlear Replacement Magnet Cassette is indicated for a recipient with the following compatible cochlear implants: CI612, CI622, CI624, CI632

## Contraindications

The non-magnetic plug/non-magnetic cassette is not indicated for use in the hearing implant unless required for MRI imaging purposes. The non-magnetic plug/non-magnetic cassette is not indicated when MRI scans are conducted on the same day as the magnet removal and replacement.

The non-magnetic plugs/non-magnetic cassettes are not indicated for a recipient with any implant except those identified in the Indications.

The replacement magnet/replacement magnet cassette is not indicated for a recipient with any implant except those identified in the Indications.

## Intended patient population

The intended patient population are recipients of compatible Cochlear hearing implants who require replacement of the existing implant magnet. There are no additional restrictions for the intended patient population of these devices in terms of age, weight, health or other condition.

## Intended users

The intended users who have direct interaction with these devices include qualified medical professionals such as surgeons and surgical nurses. The intended users of these devices who have indirect use of the device include the recipient into whom the device is implanted, and their carer where appropriate. Additionally, qualified medical professionals such as radiologists and audiologists are also intended users who have indirect interaction with the device.

## Benefits

The use of non-magnetic plugs/non-magnetic cassettes minimise the risk of infection and fibrous tissue growing into the implant recess of the respective hearing implant and ensures the recess is kept clear of debris to allow for the successful replacement of the magnet.

The replacement magnets/replacement magnet cassettes operate in conjunction with a compatible Cochlear implant system. Potential benefits of receiving a Cochlear implant system include:

- Better understanding of speech in quiet
- Better understanding of speech in noise
- Increased satisfaction based on hearing capabilities

# Troubleshooting

Please contact your clinician if the coil does not attach to your head or you experience sound quality issues.

# MRI safety information



Non-magnetic plugs, replacement magnets, non-magnetic cassettes and replacement magnet cassettes 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/replacement magnet cassettes 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/replacement magnet cassettes are identical to the MR conditions of the implants with their original magnet/magnet cassette.

Full MRI safety information is available:

- in the Cochlear Nucleus Implants MRI Guidelines
- by visiting [www.cochlear.com/mri](http://www.cochlear.com/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.

# Materials and substances

The following table lists the materials and substances used in the Cochlear Nucleus implants that come in direct contact with body tissues.

Item	Material
Cochlear CI500 Series Sterile Non-Magnetic Plug & Cochlear Sterile Non-Magnetic Plug	Titanium (grade 2)
Cochlear CI500 Series Sterile Replacement Magnet & Cochlear Sterile Replacement Magnet	Titanium (grade 2)
Cochlear Non-Magnetic Cassette	Titanium (Grade 2), Silicone elastomer
Cochlear Replacement Magnet Cassette	Titanium (Grade 2), Silicone elastomer
Cochlear CI24RE Non-Magnetic Plug	Titanium (grade 2)
Cochlear CI24RE 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 Replacement Magnet	Cobalt

## Product component measurements

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

Item	Weight g	Length mm	Width mm	Height mm
Cochlear Non-Magnetic Cassette	1.4	17	14	2.6
Cochlear Replacement Magnet Cassette	1.7	17	14	2.6

## 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](http://www.cochlear.com) or request a copy from Cochlear at the address nearest you.

# Summary of safety and clinical performance

A summary of the safety and clinical performance of the non-magnetic plugs, replacement magnets, non-magnetic cassettes and replacement magnet cassettes can be found at <https://ec.europa.eu/tools/eudamed>



# 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 any of the following:

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

## Reporting a serious incident

There is no definitive list of events/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)
- the Therapeutic Goods Administration  
<https://www.tga.gov.au>

# 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 OS1200 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.



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

ACE, Advance Off-Stylet, AOS, AutoNRT, Autosensitivity, Beam, Bring Back the Beat, Button, Carina, Cochlear, コクレア, コクレア, コクレア, Cochlear SoftWear, Codacs, Contour, Contour Advance, Custom Sound, ESprit, Freedom, Hear now. And always, Hugfit, Hybrid, Invisible Hearing, Kanso, MET, MicroDrive, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Outcome Focused Fitting, Off-Stylet, Slimline, SmartSound, Softip, SPrint, True Wireless, the elliptical logo, and Whisper are either trademarks or registered trademarks of Cochlear Limited. Ardium, Baha, Baha SoftWear, BCDriver, DermalLock, EveryWear, SoundArc, Vistafix, and WindShield are either trademarks or registered trademarks of Cochlear Bone Anchored Solutions AB.

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