

衛生署  
醫療儀器管制辦公室  
香港灣仔皇后大道東 183 號  
合和中心 31 樓 3101 室



DEPARTMENT OF HEALTH  
Medical Device Control Office  
Room 3101, 31/F, Hopewell Centre,  
183 Queen's Road East, Wan Chai, Hong Kong

本署檔號 OUR REF: S/F(167) to DH/MDCO/20-5/8  
來函檔號 YOUR REF:  
電話 TEL: 3107 8484  
電郵 EMAIL: [mdco@dh.gov.hk](mailto:mdco@dh.gov.hk)  
圖文傳真 FAX: 3157 1286

Dear Doctor,

**Voluntary Recall Notification for Nucleus CI500 cochlear implant range**

Your attention is drawn to a voluntary recall notification issued by Cochlear Limited (Cochlear) regarding Cochlear Nucleus CI500 cochlear implant range. The range includes Nucleus CI512 Implant; Nucleus CI513 Implant, Nucleus CI551 Double Array Implant and Nucleus ABI 541 Auditory Brainstem Implant.

According to Cochlear, they have identified a recent increase in the number of Nucleus CI512 implant failures. As at 9 September, 2011, 167 reports of suspected or confirmed CI512 implant failures and 1 report of suspected CI513 implant failure had been received (a total of 168) globally. Of these 168 reports, 162 are associated with reports of the recipient experiencing intermittent implant behavior that finally leads to the implant ceasing to function.

Cochlear also claimed that the only hazard associated with the reported intermittent behavior is limited to a loss or deterioration of the device function. As a precautionary measure, Cochlear is recalling all unimplanted CI500 series cochlear implants while they further investigate the cause of this issue. According to Cochlear, the affected product has been distributed in Hong Kong. Cochlear will directly contact each of the healthcare professionals to make arrangements for the return of the devices.

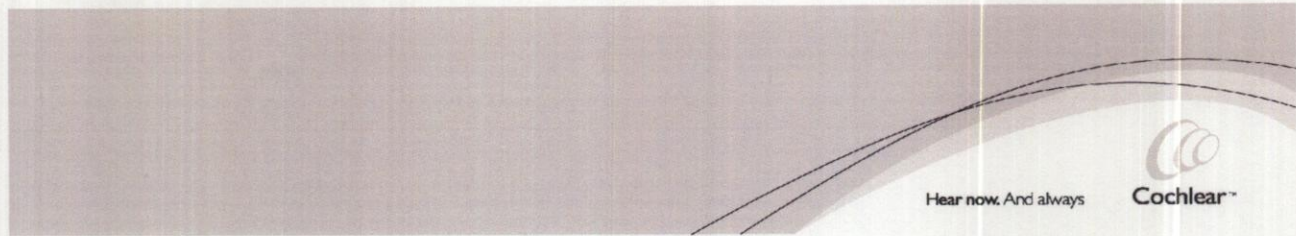
For more details, please refer to appendix 1 or contact Cochlear Hong Kong Limited at 2903 1008.

Thank you for your attention.

Yours faithfully,

(Dr. Addi CHAN)  
for Director of Health

竭誠服務 顧客為本 素質為先  
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Hear now. And always



**Cochlear Limited**  
ABN 96 002 618 073  
14 Mars Road  
PO Box 629  
Lane Cove NSW 2066  
Australia  
Tel 61 2 9428 6555  
Fax 61 2 9428 6539  
[www.cochlear.com](http://www.cochlear.com)

Recall Coordinator

**Re: Intent to Initiate Voluntary Medical Device Recall**

Dear Recall Coordinator

We are writing to inform you that Cochlear Limited wishes to undertake a voluntary recall of the **unimplanted Cochlear Nucleus CI500 cochlear implant range:**

Current Listings: 090499

While less than 1% of CI512 implants have failed since launch in 2009, Cochlear has identified a recent increase in the number of Nucleus CI512 implant failures. We include below for your reference the history of the related product issue and our proposed action plan.

**1. PROBLEM DESCRIPTION**

**a. Details of the problem:**

**i Nature and extent of the problem:**

As at Friday 9th September, 2011, 167 reports of suspected or confirmed CI512 implant failures and 1 report of suspected CI513 implant failure had been received (a total of 168) globally. Of these 168 reports, 162 are associated with reports of the recipient experiencing intermittent implant behavior that finally leads to the implant ceasing to function.

**ii. How the problem was identified / triggered**

All reports of suspected failures of CI512 and CI513 are captured in the CREM complaint management system. These reports are tracked daily by the QC&R Post Market Surveillance group.

**iii. Results of tests or other investigations that have been performed to determine the seriousness and scale of the problem.**

For the 162 cases where the reports are of implant ceasing to function, 70 of these devices have been returned for investigation. For these 70 devices 34 investigations are complete and approved through the technical review meeting process, while the remaining 36 have the investigation ongoing. The preliminary investigation has identified that components within the implant electronics assembly fail and the implant shuts down in a safe manner (that is, the implant fails safe).

There are presently 25,516 registered CI512 implants in the field globally, although 33,645 CI512 implants have been shipped from Cochlear regional warehouses to clinics.

The 162 reported cases of the CI512 implant ceasing to function equates to 0.63% of the currently registered devices.

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**b. Details of the product:**

**i. Product name:**

The product affected are the Nucleus CI500 implant range which includes the Nucleus CI512 implant plus the following implants which are only available in limited markets – Nucleus CI513, Nucleus CI551 double array implant and Nucleus ABI 541 Auditory Brainstem Implant.

**ii. Number of devices affected -**

Cochlear has shipped 180 devices to Hong Kong. Of these devices 106 have been implanted, 69 have been shipped to clinics/hospitals and 5 have been quarantined within our Hong Kong office.

**c. Risk assessment:**

Health Hazard Analysis - CI512 devices with reports of intermittent behaviour							
The analysis uses the approach of ISO14971 Risk Management for Medical Devices.							
Hazard Classification Type (Table E.1 ISO14971)	Hazard (Potential Source of harm)	Foreseeable sequence of events	Hazardous Situation	Potential harm(s)	Severity of the harm	Probability of occurrence of the harm	Risk Class (RI)
Function	Loss or deterioration of function	The recipient notices a performance decrement The recipient visits their clinic for a consultation The clinician performs a series of diagnostic tests including a Crystal IT test If the test system indicates a device failure the clinician may recommend revision surgery	There is no additional hazard resulting from the loss or deterioration of device function. The recipient may elect to have revision surgery. <i>The scientific literature reports excellent outcomes following revision surgeries [references needed]</i>	The potential harm is the surgery itself.  It should be noted that CI surgery is now a routine surgery with approximately 200,000 surgeries having been conducted since the device was first produced in the early 1980s.	Mirror*  *classification taken from Doc 123039: MULBERRY b – RISK MANAGEMENT PLAN, Minor means - Non-functioning or impaired performance (requires implant removal / replacement surgery)	Remote * [probability of harm is the probability of intermittent device behaviour (162/25516 = 0.63%)]  *classification taken from Doc 123039: MULBERRY b – RISK MANAGEMENT PLAN, Remote means 0.1% < P < 1.0%	Low*  *classification taken from Doc 123039: MULBERRY b – RISK MANAGEMENT PLAN, low comes from the combination of "Remote" likelihood and "Minor" severity

The only hazard associated with the reported intermittent behavior is limited to a loss or deterioration of the device function.

Using the approach set out in ISO14971, an evaluation of the risk associated with the reported device intermittency has been completed. The completed evaluation is presented in the table above.

From this evaluation the risk associated with the reported intermittent behaviour is "Low".

**2. SAFETY ASSESSMENT**

As of Friday 9th September, 2011 reports of suspected and confirmed implant failures (for all causes) have been received for 0.66% of registered CI512 implants. In addition, there has been a recent increase in the number of suspected Nucleus CI512 implant failures. In an abundance of caution Cochlear has made the decision to begin the actions necessary for a voluntary recall of the Nucleus CI500 range of cochlear implants while we further investigate the cause of this issue.

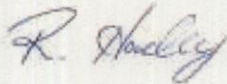
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### 3. IMMEDIATE PROPOSED ACTIONS

- I. Cochlear propose to recall all unimplanted CI500 series cochlear implants.
- II. From a clinical management perspective, the predominant symptom for the identified failures is the implant safely shutting down and ceasing to function. This failure has occurred in approximately 0.6% of registered Nucleus CI512 devices. Existing Nucleus CI500 series implant recipients can continue to use their devices as per normal and therefore we propose to not extend the recall to implanted recipients.
- III. Cochlear have drafted the proposed communication to health care professionals, hospitals and clinics. Cochlear propose to circulate the formal communication via email, fax or hand deliver where required.
- IV. Cochlear will directly contact each of the health care professionals to make arrangements for the return of the devices.

Should you require any further information, please do not hesitate to contact me on +61 2 8002 2828.

Kind regards



Renee Hardley  
Regulatory Affairs Manager  
Cochlear Limited  
Asia Pacific Region

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