Hear now. And always

Cochlear™

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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.

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 these168 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.

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 77 devices to Malaysia. Of these devices 76 have been implanted.

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. *The scientific literature reports excellent outcomes following revision surgeries [references needed]*	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.	Minor* **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.

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