

Hear now. And always



Cochlear™

Chris Roberts
CEO/President
Cochlear Limited
1 University Avenue
Macquarie University
NSW 2109 Australia

7th February 2012

Update on Nucleus® CI500 series implant recall

Dear Colleague,

This letter provides the latest information regarding the voluntary recall of unimplanted Nucleus CI500 series implants, specifically information regarding the latest observations associated with the number of reported devices failing, the failure mechanism and the clinical symptoms associated with the failure mechanism.

In December 2011, we reported the root cause for the loss of hermeticity to be unexpected variations in the brazing process that joins the feedthrough to the titanium chassis during manufacturing. These variations resulted in a limited number of implants being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps. These microcracks allow water molecules to enter the implant resulting in the malfunction of specific electronic components (typically one of four diodes). Failure of these electronic components results in the implant shutting down. This failure mechanism continues to be consistent with no other failure mechanism associated with the loss of hermeticity identified.

As of January 31st, 2012, the overall proportion of Nucleus CI500 series devices that has been reported as failed is 2.4% of registered devices globally. The number of newly reported device failures each month has decreased every month since October 2011.

For the devices that failed, the average time to failure after implantation was 7 months (90th percentile 12.0 months). Of the 97.6% of devices that have not failed, the majority (>85%) have been implanted for longer than the average time to failure. These data cannot be used to predict future failures.

Of the 2.4% of devices that have failed, two thirds were manufactured in the first quarter of 2011. Of the devices that have not failed from this manufacturing period, the majority (>75%) have been implanted for longer than the average time to failure of 7 months. Clinically the symptoms experienced prior to failure continue to be consistent i.e. a period of intermittency followed by the implant shutting down. Unless symptoms are present it is not necessary to treat patients with devices manufactured in the first quarter of 2011 any differently to your current clinical management.

We remain as committed as ever to you, our recipients and our long term mission of bringing hearing to people around the world. If you have any questions regarding this update please do not hesitate to contact your local Cochlear clinical representative.

Yours sincerely

Dr Chris Roberts
CEO/President