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Cochlear®

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7th August 2012

Update on Nucleus® CI500 series implant recall

Dear Colleague,

This letter provides updated information regarding Nucleus CI500 series implants, specifically the number of reported devices failing, latest observations associated with the failure mechanism, and status of the voluntary recall process initiated September 11, 2011.

As of July 31st, 2012, the overall proportion of Nucleus CI500 series devices reported as failed was 4.2% of registered Nucleus CI500 devices globally. For these devices, the average time to failure after implantation was 9.3 months (90th percentile was 14.7 months).

Newly reported failures each month continued falling. For example failures in July 2012 were approximately one third of the failures in the peak month of October 2011. In addition, of the 95.8% of devices that continue functioning, greater than 99% have been implanted for longer than the average time to failure of 9.3 months, (80% have been implanted longer than 14.7 months). These data cannot be used to predict future failures.

In December 2011 and February 2012, we reported the failure mechanism as a loss of hermeticity which results in the malfunction of specific electronic components (typically one of four diodes). Failure of these electronic components results in the implant shutting down. No other failure mechanism associated with the loss of hermeticity has been identified. In February 2012 we also communicated that the majority of devices reported as failed were manufactured in the first quarter of 2011. This statement still applies.

Clinically, a period of intermittency followed by device shut down is the predominant clinical symptom and is consistent with the failure mechanism.

We recently have been notified by a number of Regulatory Authorities including FDA and European Competent Authorities that all necessary actions associated with return of unimplanted CI500 series devices have been completed. We thank you for your help and support in identifying and returning unimplanted CI500 series devices.

We also would like to thank you for your support, advice and encouragement. 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