

**ASX / MEDIA RELEASE**

**20 December 2011**

**UPDATE ON NUCLEUS CI500 SERIES IMPLANT RECALL**

Attached is a letter to clinicians updating them on the Nucleus CI500 Series Implant recall.

The letter addresses the root cause analysis and the latest failure rates.

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**About Cochlear Limited (ASX: COH)**

Cochlear is the global leader in implantable hearing solutions. It has a dedicated global team of more than 2,500 people who deliver the gift of sound to the hearing impaired in over 100 countries around the world. Our vision is to connect people, young and old, to a world of sound by offering life enhancing hearing solutions.

Over almost 30 years this vision has seen Cochlear help over 250,000 people either hear for the first time or reconnect them to their families, friends, workplaces and communities.

To this end, Cochlear offers solutions for different types of hearing loss. These include: cochlear implants, bone conduction implants, implants for electro-acoustic stimulation, auditory brain stem implants and implants for direct acoustic stimulation. Whether these hearing solutions were implanted 25 years ago or today, the company's commitment to backward compatibility ensures new upgrades and innovations can be offered to Cochlear recipients.

Cochlear's mission of "Hear now. And always" embodies the company's commitment to providing its recipients with the best possible hearing performance today and for the rest of their lives.

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Hear now. And always



Cochlear™

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December 20, 2011

**Update on Nucleus® CI500 series implant recall**

Dear Colleague,

This letter updates progress on investigations associated with the voluntary recall of unimplanted Nucleus CI500 series implants, specifically information on root cause of the loss of hermeticity.

The results of our investigation to date point to a loss of hermeticity from unexpected variations in the brazing process during manufacturing. Brazing is the process that joins the feedthrough to the titanium chassis. Variations in the brazing process have 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).

This understanding of the root cause now forms the basis of the plan for the return of the Nucleus CI500 series implant to market.

The overall proportion of CI500 series devices that has failed is approximately 1.9% of registered implants globally with similar percentages in all three regions (The Americas, Europe Middle East & Africa (EMEA) and Asia Pacific). There were fewer reported failures in November 2011 than in October 2011.

As we have stated previously, the Nucleus CI24RE and Nucleus CI422 series implants are not affected by this failure mechanism. The manufacturing process, including brazing, is different between the Nucleus CI500 series and Nucleus CI24RE and CI422 series. There are over 62,000 registered Nucleus CI24RE devices globally and this failure mechanism has never been reported.

Again I would like to express my sincere thanks for your ongoing support. If you have any questions regarding this letter or any of our customer updates please do not hesitate to contact your local Cochlear clinical representative.

Yours sincerely

Dr Chris Roberts  
CEO/President

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