Hear now. And always

Cochlear™

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Update on Nucleus® CI500 series implant recall

Dear Colleague,

This is an update on the progress of our investigations associated with the voluntary recall of unimplanted Nucleus CI500 series implants.

To date approximately 1.5% of the globally registered Nucleus CI500 series implants have failed. We have identified that all of the returned implants with analysis complete failed due to a malfunction of specific electronic components associated with the receipt and management of information and power from the sound processor. When these components malfunction the implant shuts down. Our investigation shows that these electronic components appear to malfunction due to the presence of moisture resulting from a loss of hermeticity. The cause of the loss of hermeticity is under further investigation.

A thorough review of all the clinical reports associated with failed devices has been completed. In all failed devices, recipients experienced intermittency or no sound prior to failure which is consistent with the failure mechanism outlined above. In addition some 80% experienced a connection issue at the clinic. We have also observed that the time between onset of symptoms and device failure is relatively short and in the majority of cases failure occurs within 30 days of reported onset of symptoms. While the symptoms are consistent, our investigation is ongoing, and we encourage you to continue reporting any unusual clinical symptoms that are not rectified through normal clinical practice. As a reminder, all reports of intermittency or no sound require careful troubleshooting to resolve any possible external hardware or programming issues as not all intermittencies will be associated with the implant.

Analysis has also been conducted to ascertain if there is any difference in the proportion of failures between children (< 3 years old) and adults compared to the age distribution of the total recipient base. To date there is no statistically significant difference and the recipient age distribution of failures correlates closely to the overall recipient population. We have also examined the time to reporting of symptoms between children (<3 years old) and adults. There is also no statistically significant difference between reporting of onset of problem between children (<3 years old) and adults.

Our manufacturing ramp up of the Nucleus CI24RE and Nucleus CI422 implants is progressing very well. We thank you for your support and understanding as we manage current supply to surgery. We are doing everything possible to ensure you have all the Nucleus CI24RE and Nucleus CI422 implants you require and to minimise any impact on scheduled surgery dates.

We have been asked how we can be confident that the Nucleus CI24RE and Nucleus CI422 implants do not have similar reliability problems to the Nucleus CI500 series. Whilst the implants are functionally the same, the mechanical design, manufacturing process and manufacturing line used for Nucleus CI24RE and Nucleus CI422 is different to the Nucleus CI500 series implants. In over 62,000 registered CI24RE / CI422 devices globally there has never been a report of a failure with the same failure mechanism identified in the Nucleus CI500 series. We are confident in the reliability of the Nucleus CI24RE series which sets the industry benchmark with a 7 year Cumulative Survival Percentage of 99.0%.

Again I would like to express my sincere thanks for your support during this challenging situation. 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
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