



本署檔號 OUR REF: S/F(167) in DH/MDCO/20-5/8
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Dear Doctor,

Voluntary Recall Notification for Nucleus CI500 cochlear implant range

Your attention is drawn to a voluntary recall notification issued by Cochlear Limited (Cochlear) regarding Cochlear Nucleus CI500 cochlear implant range. The range includes Nucleus CI512 Implant; Nucleus CI513 Implant, Nucleus CI551 Double Array Implant and Nucleus ABI 541 Auditory Brainstem Implant.

According to Cochlear, they have identified a recent increase in the number of Nucleus CI512 implant failures. As at 9 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 these 168 reports, 162 are associated with reports of the recipient experiencing intermittent implant behavior that finally leads to the implant ceasing to function.

Cochlear also claimed that the only hazard associated with the reported intermittent behavior is limited to a loss or deterioration of the device function. As a precautionary measure, Cochlear is recalling all unimplanted CI500 series cochlear implants while they further investigate the cause of this issue. According to Cochlear, the affected product has been distributed in Hong Kong. Cochlear will directly contact each of the healthcare professionals to make arrangements for the return of the devices.

For more details, please contact Cochlear Hong Kong Limited at 2903 1008.

Thank you for your attention.

Yours faithfully,

(Dr Addi Chan)

for Director of Health