

URGENT FIELD SAFETY NOTICE

20 December 2018

Potential mis-packaging of Baha Tamper-proof Battery Door

What has happened?

Cochlear Bone Anchored Solutions AB has received some feedback from clinics in Australia, that packages of the item P1129017 (Baha 5 Sound Processor Tamper-proof battery door 3pcs) contained standard doors instead.

Who is impacted?

According to our records, your clinic has recently ordered items from the same 50 piece LOT, numbered COH1253733. As LOTs are packaged at the same time there is a chance that all products in this LOT might have standard battery doors instead of Tamper-proof.

What does it mean for you?

The Tamperproof Battery Door is used to avoid that users, especially children, unintentionally gets exposed to small parts. The instruction included in the package says: Before use, verify that the tamper-proof battery door is locked. This instruction is also included in mis-packaged items. We also believe that patients who are familiar with the Baha 5 Tamper-proof solution, will detect that they have received the wrong door and not use it and we would kindly ask you take the actions listed below.

What do you need to do?

- 1) Should you have any battery doors from the mentioned LOT, COH1253733, in your possession please scrap or return these to Cochlear.
- 2) If you are getting complaints or queries from your patients about "loose battery doors" or similar, please advise them to return the battery door to your clinic.
- 3) Please try to identify patients who have received the Tamper-proof battery doors from the affected LOT. Please contact these patients and arrange a return.

Your Cochlear representative will be in contact over the coming weeks to offer support and to confirm completion of the above actions.

For audit purposes, please complete the Customer Acknowledgement below and return to Cochlear as soon as possible.

Cochlear sincerely apologises for the inconvenience caused by this issue and please find enclosed full replacement stock as per your original order.