

CAPA Communication to Clinics

FIELD SAFETY NOTICE

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 two 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 Tamper-proof battery door is used to prevent patients, especially children, from being exposed to small parts. Our Baha 5 User Manual asks that you check the functionality before using the Tamper-proof battery door. As per our instructions for use, please be reminded that children should be carefully supervised at all times when using the Baha 5 Sound Processor.

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 you have the option to 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.