21/10/2021

URGENT MEDICAL DEVICE RECALL

Medsafe Recall Reference Number: #28493
Product name: Oticon Medical Neuro Zti EVO and CLA Implants

Dear Oticon Medical Cochlear Implant Recipient,

First, we want to thank you for choosing Oticon Medical. Empowering you to hear is the cornerstone of what we do, and we want to assure you that safety, product quality, hearing outcomes and lifelong support are our highest priorities.

This recall is only for **non-implanted** Neuro Zti devices. The purpose of this letter is firstly, to assure you that you can continue to safely hear and use your Neuro Cochlear Implant System.

Oticon Medical has identified a recent increase in the number of failures with the Neuro Zti cochlear implant and although the failure rate of the device is extremely low (less than 1%), we decided to react as quickly as possible and recall all **non-implanted** Neuro Zti devices from clinics while we further investigate the problem.

*The following **non-implanted** implants are being recalled:*

1. Neuro Zti Cochlear Implant – Evo

   Catalogue No - M80185 - SN from and above NZB04074

2. Neuro Zti Cochlear Implant – Classic

   Catalogue No. – M80184 - SN from and above NZA02454

The serial number (SN) is found on your patient ID card.

Oticon Medical, after consultation with Medsafe, is conducting a recall of the above **non-implanted** Neuro Zti EVO and CLA implants. We are contacting you as the potentially affected product has been supplied to you.

If your implant has a corresponding serial number, then please do not be alarmed, on the rare occasion an implant stops working, the implant shuts down causing no harm or safety risk, but no sound will be heard while wearing the sound processor. It is important to know that this recall only affects the **non-implanted** Neuro Zti internal implant (with the above-mentioned serial numbers) and does not affect any of the external sound processors or accessories or earlier SN's.

Due to the extremely low risk of the issue, implants <u>will not</u> be explanted from patients as part of this recall. There are no hazard, safety or adverse events reported in the case of failure.

No other Oticon Medical product is affected.

WHAT DOES THIS MEAN FOR YOU?

You should continue to use your device as normal. If you, experience any issues in sound quality, this is most likely associated with your external sound processor. You should follow the normal sound processor troubleshooting which will almost certainly rectify the problem. This troubleshooting includes checking the sound processor, the cable, the antenna, and the battery. It is important to check one piece of equipment at a time to isolate the likely problem.

If you experience a sudden loss of communication, and the problem cannot be isolated to the external components mentioned above, then additional troubleshooting at the clinic will be required. In this instance we recommend you, at your earliest convenience, contact your clinic where additional troubleshooting and further checks will be performed to isolate the issue.

We ask you to complete the attached acknowledgement form **immediately,** and return it to info@oticonmedical.co.nz to reconcile this process.

We recognise you may have concerns or questions. To help address these you can contact your local Oticon Medical representative or the local Oticon Medical Customer Service at 0800 864 795 or info@oticonmedical.co.nz for further support.

With more than 25 years of cochlear implant experience and with more than a century of commitment to hearing health, please rest assured that your hearing and cochlear implant reliability is of paramount importance to Oticon Medical. We are truly sorry for any concern and disruption this may cause you or your family. We would like to reassure you that we, together with Demant - our mother company and one of the world's largest hearing healthcare groups - are committed to providing you with lifelong support.

Kind Regards,

Tracey King

Business Unit Manager – ANZ

Oticon Medical