

14<sup>th</sup> October 2021

## Information on Voluntary Field Corrective Action “211014”

### Oticon Medical Neuro Zti cochlear implant

Dear Oticon Medical Cochlear Implant Recipient

First, we want to thank you for choosing Oticon Medical. Empowering you, or your child, 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.

You may recently have learned that Oticon Medical has made a voluntary recall of one of our implants – the Neuro Zti cochlear implant. This recall is only for **unimplanted** Neuro Zti devices and does not affect the Digisonic implants. The purpose of this letter is firstly, to assure you that **you, or your child, can continue to safely hear and use your Neuro Cochlear Implant System.**

Secondly, this letter is to tell you why we are voluntarily recalling one of our implants. 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 unimplanted Neuro Zti devices from clinics while we further investigate the problem. The recall affects implants with a serial number above NZB04074 (Neuro Zti EVO) and those with a serial number above NZA02454 (Neuro Zti CLA). The serial number (SN) is found on your patient ID card.

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 unimplanted Neuro Zti internal implant (with the above-mentioned serial numbers) and does **not** affect any of the external sound processors or accessories.

#### WHAT DOES THIS MEAN FOR YOU?

You should continue to use your device as normal. If you, or your child, 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, or your child, 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 recognise you may have concerns or further questions. To help address these you can contact your local Oticon Medical representative or the local Oticon Medical Customer Service 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,  
Oticon Medical



Cédric Briand  
General Manager, CI