

1<sup>st</sup> March 2022

## **Notification of Expected Return to Market Oticon Medical Neuro Zti cochlear implant**

Dear Oticon Medical Cochlear Implant Recipient

We want to thank you for choosing Oticon Medical as your Cochlear Implant supplier. Empowering you, or your child, to hear is the cornerstone of what we do, and we want to assure you that safety, product reliability, hearing outcomes and lifelong support are our highest priorities.

You may recently have learned that Oticon Medical voluntarily withdrew the Neuro Zti cochlear implant from circulation. Oticon Medical took this action because we had identified a small number of devices that were not completely air- and liquid-tight. We withdrew all non-implanted devices from hospitals and clinics around the world while we investigated the problem. The number of faulty devices has remained low at 2%. There have been no safety events reported with these devices.

As an existing Neuro Zti user, and as long as you have no symptoms of implant failure, you are still advised to continue to use your device as normal since the prevalence of the problem was very low and there were no reports of safety events. If you, or your child, experience issues in sound quality, this is most likely associated with your external sound processor. The implants at fault have been identified by an unexplained loss of communication between the sound processor where normal troubleshooting procedures (checking the sound processor, the cable, the antenna, and the battery, one piece at a time) are ineffective in solving the problem. In this instance you should visit your hearing clinic for further checks.

We are happy to say that we identified the cause of the problem as relating to small irregularities in the production process. The problem did not originate in the design of the implant. We have been able to correct these irregularities and are implementing additional, stringent production and testing processes to prevent similar issues from occurring again.

We will submit the necessary documentation to the relevant health authorities and expect the Neuro Zti to be back in CI clinics and hospitals from the third quarter this year.

Therefore, we hope with this notification, that you will feel confident as a Neuro System user. The reliability of Neuro Zti implant is among the best on the market, and whilst this issue has dented the reliability record slightly, we can expect the Neuro Zti to continue to be one of the most reliable cochlear implants available in the future.

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 at +33 (0)4 93 95 3819 or [OM\\_CI\\_Global@oticonmedical.com](mailto:OM_CI_Global@oticonmedical.com) where you will find someone eager to help you.

Oticon Medical has more than 25 years of cochlear implant experience and is an integral part of one of the world's largest hearing healthcare groups, Demant, who've been committed to hearing health for over a century. We are truly sorry for any concern and disruption we may have caused you or your family. We would like to reassure you that, at Oticon Medical, we are still fully committed to providing you with lifelong support.

Kind Regards,  
Oticon Medical



Cédric Briand  
General Manager, CI