

1st March 2022

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

Dear Customer

We are writing to inform you of the return to market of the Neuro Zti cochlear implant.

On 14th October 2021 Oticon Medical voluntarily withdrew non-implanted Neuro Zti CI implants from circulation due to the identification of a number of implants exhibiting a loss of hermeticity. The issue was attributed to a small number of devices from specific batches and to date, 54 implants have been identified with a loss of hermeticity or are under surveillance for loss of hermeticity, representing a continued low incidence rate of 2%. All potentially affected non-implanted devices were removed from circulation worldwide on the day of the notification.

Users of faulty devices experienced a safe shutdown of their system detected by complete loss of communication between the sound processor and the implant where normal troubleshooting procedures were not able to solve the issue. There were no additional symptoms, and no reported safety events. Existing Neuro Zti recipients with no symptoms of implant failure were advised to continue to use their device as normal since the prevalence of the problem was very low and there were no reports of safety events.

A thorough analysis was started immediately to identify the root cause.

The root cause has been identified as pertaining to deviations in the production process – and not the design of the implant. Our analyses showed that slight deviations from the defined temperature range in the high vacuum production oven had caused tiny irregularities that resulted in micro-leakage. Corrective and preventive actions are being implemented and we are confident that our production and quality systems are performing optimally.

All processes and procedures in our Quality Management System have been optimised and refined to ensure the best possible product quality and reliability. It is important to note that the sign of a robust quality system is not in its ability to eliminate any and all problems, or to make unrealistic promises. Rather, a robust quality system is one that is able to catch and react appropriately to problems quickly and learn from them.

The necessary information will be submitted to all relevant regulatory and health authorities; we expect the Neuro Zti to be back on the market from Q3-2022 with an expected start in the first markets from July 2022. Exact timelines are dependent on the length of the regulatory authorities' process and the relevant health authority in the countries concerned. We will revert with more exact timing for your clinic as soon as possible.

Oticon Medical remain committed to patient safety, product reliability and open and honest customer dialogue. We apologise greatly for any disruption this has caused you and your patients.


As we may not have e-mail contact details for everyone at your clinic or facility, we ask you to please forward this letter to relevant colleagues.

We hope with this notification that you feel confident in working with Oticon Medical. As the referral path to CI treatment can take months, we hope that you will restart counselling candidates on the Neuro System as soon as we have reverted with an expected date for your clinic.

If you have any further questions, please call your local Oticon Medical representative on:
+33 (0)4 93 95 3819

Please rest assured that at Oticon Medical, we are committed to designing and manufacturing high-quality products and we will continuously strive to improve product performance and patient outcomes.

Kind Regards,
Oticon Medical



Cédric Briand
General Manager, CI