October 14th, 2021

Notification of Voluntary Field Corrective Action "211014"

Oticon Medical Neuro Zti cochlear implant

Dear Customer

We are writing to inform you that Oticon Medical has decided to undertake a **voluntary recall of all non-implanted Oticon Medical Neuro Zti EVO implants with a serial number from NZB04074 and above, and of all non-implanted Oticon Medical Neuro Zti CLA implants with a serial number from NZA02454 and above**. This recall affects both 1.5T and 3.0T MRI compatible implants. There is no safety issue related to this recall.

While the Cumulative Survival Percentage (CSP) of the Neuro Zti implants is 99,25% after 6 years according to the European Consensus Statement on Cochlear Implant Failures and Explantations[1], the Oticon Medical quality system has recently identified an increase in the number of Neuro Zti device explants or under surveillance to be explanted because of a loss of hermeticity.

The explantations have been performed after reports of complete loss of communication between the implant and the sound processor, and investigations have confirmed a loss of hermeticity. There have been zero reported safety events with these devices, and Oticon Medical has not received any safety-related complaints from recipients.

The rising trend of early failures compared to the baseline is the reason for this voluntary recall. Our investigations have shown that it relates to a manufacturing deviation affecting potentially 3,976 Neuro Zti implants. By October 13th, 2021, 28 implants of these 3,976 have either been explanted or are under surveillance to become explanted.

As patient safety, hearing performance, and reliability of our products is of utmost importance, Oticon Medical has taken the decision to act as quickly as possible - even though the prevalence of the problem is low. We therefore issue a voluntary recall of the **non-implanted devices** to ensure that potentially affected implants will not be implanted and to allow time for further root cause analysis and corrective actions.

It is important to state that there are **no safety concerns for current recipients implanted with the affected implants**. Most Neuro Zti recipients are not likely to experience the problem as the prevalence of the problem is very low. Our clinical support teams around the world will have a special focus on monitoring affected Neuro Zti recipients and on following up, should the problem occur. Oticon Medical will provide special information to recipients and caregivers on this matter.

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[1] Oticon Medical Reliability Report June 2021 (224811UK – version B / 2021.09). Calculated since the launch in 2015 including accident-related issues and combined for EVO/CLA implants according to the European Consensus Statement on Cochlear Implant Failures and Explantations, Otol Neurotol. 2005 Nov, 26(6):1097-9. For more information on reliability: https://www.oticonmedical.com/for-professionals/cochlear-implant/reliability-report

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S.A.S. au capital de 1.000.000 €

IMMEDIATE ACTIONS AND IMPORTANT INFORMATION:

1) Oticon Medical recalls all **non-implanted** Neuro Zti implants with a serial number above NZB04074 (Neuro Zti EVO) and above NZA02454 (Neuro Zti CLA) from circulation.
2) From a clinical management perspective, the predominant symptom for the identified failure is the implant safely shutting down and ceasing to function (complete loss of communication) even after normal troubleshooting and trial with a new sound processor and a new antenna cable. As there is no safety risk, it is **recommended that existing Neuro Zti recipients continue to use their devices as per normal** and therefore Oticon Medical does not recommend a device explantation, as the device may work as intended for the expected lifetime.
3) Oticon Medical is taking additional steps for further root cause analysis. We do not know how long this process will take but, until it is completed, we will not be supplying Neuro Zti implants. Please be assured that we are working as quickly as possible to resolve the issue. If you have a candidate scheduled for cochlear implant surgery, we recommend that you use a cochlear implant from another manufacturer or postpone surgery. We deeply regret the inconvenience this interruption will cause you and your patients.
4) Oticon Medical is committed to notifying, as quickly as possible, all relevant health care professionals, hospitals, and clinics. Notification will be via e-mail or telephone in the first instance and followed up with personal visits where required. Our Clinical Support teams are ready to support you in this situation and whenever you may need it.
5) Oticon Medical will directly contact each of the implanting clinics to make arrangements for the return of the non-implanted devices.
6) Neuro Zti implants manufactured before the manufacturing deviation occurred are not included in this recall. This means that Neuro Zti EVO implants with a serial number below NZB04074 and Neuro Zti CLA implants with a serial number below NZA02454 are **not** included in this recall.
7) Digisonic SP implants or previous implant generations are **not** included in this recall.

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 will put all our efforts into understanding and solving this issue and we will continue to be transparent in our communication. If you have any questions regarding this letter, please call:

1) Your local Oticon Medical representative
2) The Oticon Medical Global Support Line (available Monday - Friday between 6am and 6pm (CET): Phone +33 (0)4.93.95.38.19 or email: OM_CI_Global@oticonmedical.com

We are truly sorry for any disruption this causes you and your patients. 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.

To ensure the effectiveness of this communication, please acknowledge receipt of this communication by replying to the sender (via e-mail) confirming receipt at your earliest convenience.

Kind Regards,
Oticon Medical

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General Manager, CI

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