

Company announcement no 2021-16

20 December 2021

**Update on voluntary field corrective action
by the cochlear implants business**

As previously communicated on 14 October 2021, Oticon Medical, which constitutes the Hearing Implants business in the Demant Group, has initiated a voluntary field corrective action by recalling a number of non-implanted Neuro Zti cochlear implants and has temporarily halted sales of new implants.

While uncertainties still exist, we believe that we have now identified the root cause of the issue, which is related to the manufacturing process and not the design of the implants. We are currently working on implementing and verifying a solution to the issue to ensure high and consistent process quality. Based on our current assessment, we now expect sales activities to be resumed in Q3 2022 and ramped up in the subsequent months. This expected timeline is subject to final verification and validation, including approval by relevant external bodies.

Until implant sales are resumed, revenue generated by Hearing Implants will comprise sales of external cochlear implant sound processors to existing users as well as bone anchored hearing systems, which are still expected to remain unaffected. As previously communicated, such continuous sales accounted for around 65% of total revenue for Hearing Implants prior to the voluntary field corrective action.

In mid-October, investigations showed that up to 3,976 Neuro Zti implants were potentially affected and that a total of 28 implants had either been explanted or were at that time under surveillance to be explanted. As of 19 December 2021, the latter number had increased to 43 implants. So far, the number of reported incidents has thus remained low, and most users are unlikely to experience any issues. There have still not been any reported safety events in relation to the implants, and there are still no safety concerns for existing users.

There are no changes to our previous assessment that the voluntary field corrective action will result in one-off costs of around DKK 70-100 million in 2021.

Unless the timeline for the resumption of implant sales mentioned above changes, or unless other developments require us to give an update, we do not expect to provide further separate updates on the voluntary field corrective action.

Please reach out to the contact persons listed below with any questions. As per our financial calendar, our Annual Report is scheduled for release on 8 February 2022.

Further information:

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