Advanced Bionics

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An update to the Voluntary Field Corrective Action of HiRes Ultra and Ultra 3D

Valencia, CA, Oct. 31, 2022 – Advanced Bionics (AB), a global leader in developing advanced cochlear implant systems, is providing this update on the field corrective action related to the initial version of HiRes Ultra and Ultra 3D cochlear implant devices due to a decrease in performance experienced by a portion of its recipients.

As a follow up to our February 2020 communication regarding the HiRes Ultra / HiRes Ultra 3D cochlear implant field action, we would like to update our recipients on the monitoring of the field action, as well as the performance of the newest version of the Ultra implant that replaced the original version.

As a reminder, this voluntary field action was performed in response to observed changes in device function and recipient hearing performance. The issue was identified as fluid impacting the implant electrode, resulting in an interruption of stimulation and degraded performance. While this issue does not lead to recipient injury, it may require revision surgery.

The key indicators of a device-related issue are decreased hearing performance, specifically decreased audibility, distorted loudness perception, speech clarity, and general responsiveness to sound. Recipients experiencing any of these symptoms should contact their audiologist or other healthcare provider.

As of April 5, 2022, the global rate of explant of the original version of the HiRes Ultra / HiRes Ultra 3D implant associated with this performance issue is 11.3% of the devices implanted. Advanced Bionics will continue to track the performance of original HiRes Ultra / Ultra 3D implant.

In response to early indications of the original Ultra / Ultra 3D implant performance issue, AB made device improvements to protect against fluid impacting the electrode. This improved device, known as “version 2,” has been implanted more than 14,000 times as of April 5, 2022. To date, the “version 2” device has performed at a much higher reliability level than the original design, with only one (1) of the version 2 devices explanted for performance issues similar to the now-recalled version 1 of the device as of the April date. This suggests that the “version 2” of Ultra effectively addresses the issue seen in the original design.

We continue to monitor this issue vigilantly and will continue to make updated information available. We encourage recipients to contact their local Advanced Bionics representative with any questions. AB recognizes that this issue is disruptive to the lives of recipients who have experienced related issues with their devices. We are committed to the design and manufacture of high-quality products and will work to maintain recipient confidence in our company and our products.

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