

Urgent Field Action Notification Advanced Bionics HiRes Ultra / HiRes Ultra 3D

Feb 18, 2020

Dear Customer,

The Advanced Bionics quality system has detected an increase in the number of initial HiRes Ultra and HiRes Ultra 3D device explants or the potential to be explanted as a result of a performance issue. The explants have been performed after impedance drops and reports of hearing performance degradation. In a small number of cases, fluid ingress at the electrode can occur leading to interruption of stimulation. The hermetic seal has been shown to be intact. There have been zero reported safety events with these devices relative to this issue, and AB has not received any safety-related complaints from recipients.

As of February 11, 2020, the global rate of explant of the HiRes Ultra / HiRes Ultra 3D product associated with this performance issue is less than 0.5% of the more than 16,000 devices implanted. Advanced Bionics is announcing a voluntary field corrective action in order to remove the affected version of the HiRes Ultra and HiRes Ultra 3D products from circulation. Please be aware that any HiRes Ultra or HiRes Ultra 3D cochlear implant with a Serial Number **BELOW 2000000 SHOULD NOT BE IMPLANTED**.

In our efforts to continually improve our products and upon observing the early, low-frequency rate of this performance issue, AB developed several improvements to the device to address the issue. AB has received regulatory approval from the FDA in the US and TÜV SÜD in Europe for these improvements. AB is in the process of submitting the new version to additional global regulatory agencies, and plans to distribute products in these geographies as soon as approvals are obtained. AB will continue to distribute the HiRes 90K Advantage cochlear implant as well as the improved version of HiRes Ultra and HiRes Ultra 3D based on market availability.

In the next few days, we will be providing you with additional information including a list of affected devices at your facility affected by this voluntary field action. We are contacting you now to ensure that any HiRes Ultra or HiRes Ultra 3D cochlear implant with a Serial Number **BELOW 2000000 is not implanted**.

In the meantime, as we may not have email contact information for each surgeon at your facility who implants Advanced Bionics' devices, we would appreciate you forwarding this letter to other surgeons at your facility who you are aware implant Advanced Bionics' devices.

We will continue to vigilantly monitor this issue and will be transparent in our communications. If you have any questions regarding this letter, please call Advanced Bionics:

In the United States: (877) 829-0026 between the hours of 5:00 AM and 5:00 PM Pacific Time, Monday through Friday.

For Europe / Asia Pacific / Latin America / Middle East and Africa: Please contact your local Advanced Bionics office with any questions.

We are sorry for any disruption this causes you and your patients. We are committed to the design and manufacture of high quality products and will work to maintain your confidence in our company and products.

In order to assure the effectiveness of this communication, please complete the enclosed acknowledgment form and return it to us via email, confirm@advancedbionics.com, at your earliest convenience.

Sincerely,



Mrs. Victoria CarrBrendel, PhD.
President/GVP Cochlear Implants, Corporate General Management
28515 Westinghouse St,
Valencia, CA 91350