

## **Important Notification To HiRes Ultra / Ultra 3D Cochlear Implant Recipients**

February **X**, 2020

Dear Cochlear Implant User or Parent / Caregiver,

The purpose of this letter is to provide you with information about a performance issue with the HiRes Ultra / Ultra 3D cochlear implant that could possibly affect your device. Although the vast majority of Advanced Bionics cochlear implants function properly, we have been told by Advanced Bionics that some recipients have experienced prolonged hearing degradation due to physiological fluid entering into the electrode (not the hermetic seal of the device body) and causing interruption of stimulation that can negatively affect device performance. As a precaution, after a recent increase in performance complaints, AB voluntarily initiated a removal from the market all of the initial version of unimplanted HiRes Ultra / Ultra 3D on February 18, 2020. Importantly, this performance degradation does not affect the safety of the device but revision surgery may be necessary due to the performance decrease.

In keeping with our commitment to our patients, we are now notifying those already implanted with HiRes Ultra / Ultra 3D products. Our records indicate that you are one of those patients.

**What does this mean for you?** You should continue to use your device as normal. If you experience a decrease in hearing performance over time, you should visit your Audiologist to have your hearing assessed to understand if there could be a potential issue with your cochlear implant.

**What are the signs and symptoms that HiRes Ultra / Ultra 3D might have an issue?** You or your child may experience:

- Hearing performance degradation over time
- Loss of audibility, particularly in high frequencies

**What should I do if I or my child has any of these signs or symptoms?**

1. Schedule an appointment with your Audiologist to have your hearing assessed.
2. If it is found that your hearing has decreased your Audiologist will try to reprogram your device to resolve the issue.
3. If reprogramming is not successful, your device will be tested to see if it is working properly.

**Do I need to do anything if I don't have these signs or symptoms?** No. We understand the vast majority of devices function properly and we will continue to monitor in your regular visits.

In the event that your implant is subject to this issue, Advanced Bionics will provide a replacement device, based upon market availability, free of charge that incorporates several improvements to specifically address this issue. If you have any questions regarding this letter, please call your clinic or contact your local Advanced Bionics Clinical Specialist. We are fully committed to providing you with support, information, and innovation to help improve hearing outcomes today and tomorrow.

Sincerely,