

February 21, 2020

Dear Cochlear Implant User or Parent / Caregiver,

The purpose of this letter is to provide you with information about a device issue with the HiRes Ultra / HiRes Ultra 3D cochlear implant that could possibly affect the performance of your device. Although the vast majority of Advanced Bionics cochlear implants function properly, we have become aware that some recipients have experienced prolonged hearing degradation due to body fluid entering into the electrode (not the hermetic seal of the implant case) and causing interruption of stimulation that can negatively affect device performance. AB's primary concern is the safety and hearing performance of you, our patients, as well as the reliability of our products. As a precaution, after a recent increase in performance complaints, we initiated on February 18, 2020, a voluntary removal from the market all of the initial versions of unimplanted HiRes Ultra / HiRes Ultra 3D. Please note that this device-related issue may manifest in performance degradation that could require revision surgery. The only potential for patient harm are the risks associated with a surgery.

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

What does this mean for you? You should continue to use your device as normal. If you or the person you care for 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 / HiRes Ultra 3D might have an issue? You or your child may experience:

- Hearing performance degradation over time
- Reduced ability to hear high pitched sounds (For example, "f" or "s" sounds)
- Young children or non-verbal recipients may not respond consistently to high pitched sounds

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, not at this time. We work with Physicians and Audiologists to track device reliability and the vast majority of devices function properly.

In the event that your implant is subject to this issue, Advanced Bionics will provide a replacement device free of charge that incorporates several improvements to specifically address this issue. If you have any questions regarding this letter, please contact your local Advanced Bionics representative, or our customer service department at (877)-829-0026, Customerservice@advancedbionics.com. We are fully committed to providing you with support, information, and innovation to help improve hearing outcomes today and tomorrow.