Urgent Field Action Notification

HiRes Ultra / HiRes Ultra 3D

February X, 2020

Dear <merge in customer name>,

The Advanced Bionics quality system has detected an increase in the number of initial HiRes Ultra and 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. AB's primary concern is the safety and hearing performance of our patients as well as the reliability of our products. 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 Ultra / Ultra 3D product associated with this performance issue is less than 0.5% of the more than 16,000 devices implanted. Despite this recognized performance issue with some of the initial version, the vast majority of Ultra and Ultra 3D implants continue to function properly.

Affected serial or lot number range: All serial numbers between 1000000 - 1999999

For affected recipients, the issue typically presents with low impedances (≤ 3.5 kOhms) on several (≥4) basal electrodes. The impedance changes may also be associated with a change in NRI response amplitude, audibility, loudness growth, and speech understanding. Some cases are addressed through standard program adjustments, such as increasing stimulation levels, disabling affected electrodes, or employing SPAN. However, if you are unable to resolve the issue with programming or suspect the function of the implant has been compromised, please contact your local AB representative to schedule a case review and, as appropriate, an integrity test. For more information on patient management please see Appendix A, attached to this document.

Advanced Bionics is announcing a voluntary field corrective action in order to remove the affected version of the Ultra and Ultra 3D products from circulation. 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 Ultra 3D based on market availability.

Included is a list of HiRes Ultra / Ultra 3D cochlear implants that were shipped to your clinic and are not yet registered with Advanced Bionics. Do not implant any of these units if they are still in your possession. Please follow the instructions on the Unregistered Device List provided to specify the location of each device, return all unimplanted devices and register those devices that have been implanted. A registration form has been provided for your convenience.

Also included, please see a template of a letter that, at your discretion, you may send to your patients who have been implanted with the initial version that may be subject to this issue.

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

Advanced Bionics AG
Laubisrütistrasse 28, 8712 Stäfa
Switzerland
Mrs Kemine Hale
Kemine.hale@advancedbionics.com
+41 58 928 78 00

In order to assure the effectiveness of this communication, please complete the enclosed acknowledgement form and return it to us at your earliest convenience via email to:

confirm@advancedbionics.com

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.

Sincerely,

ADVANCED BIONICS
POWERFUL CONNECTIONS

UNREGISTERED DEVICE LIST

Urgent Field Action Notification HiRes Ultra / HiRes Ultra 3D

At this time our records indicate you have the following devices in your inventory. Please use this document to specify the location of each device and return the document via email to confirm@advancedbionics.com at your earliest convenience.

Model Number	Serial Number	To Be Returned	Implanted	Lost

I certify the above information is accurate and complete to the best of my knowledge at this time.

_____ _____

Clinic/Hospital/Office Name Print Name and Title

_____ _____

Signature Date

Additional Instructions:

- **To Be Returned devices**
  If the device is in your inventory please contact your local Advanced Bionics representative to request an RMA number to return the device.
- **Implanted devices**
  If the device has been implanted and you have not registered it, please complete the attached Registration Form and return to Advanced Bionics according to the form. You may copy the Registration Form should you have more than one device to be registered.

ACKNOWLEDGEMENT FORM
Urgent Field Action Notification HiRes Ultra / HiRes Ultra 3D
February 21, 2020

Dear <merge in customer name>,

Please sign this form and return it to us at your earliest convenience via email to:

confirm@advancedbionics.com

I have read and understood the notification dated February 21, 2020 regarding the HiRes Ultra / HiRes Ultra 3D cochlear implant field action.

_____
Surgeon/Clinic/Hospital/Office Name

_____
Print Surgeon/Audiologist Name and Title

_____ _____
Signature of Surgeon/Audiologist Date

APPENDIX A: Patient Management Information

Patient Summary

The issue described in the letter above can potentially impact audibility and speech understanding for recipients of the initial HiRes Ultra / Ultra 3D implant. The pattern typically presents after more than 9 months of use as a dropping impedance to low values (≤ 3.5 kOhms) on 4 or more electrodes, most commonly on the basal end of the array (e.g. 13-16). There have been reports ofcases being resolved with program changes. However, some cases have required a revision surgery.

Key Clinical Questions

How can I identify this issue in my patients?

Typically, the issue presents as one or more of the following:

- Significantly decreasing impedances to levels below 3.5 kOhms on 4 or more electrodes
  - The affected electrodes are typically on the basal end of the array (e.g. 13-16)
  - NRI responses reduced or absent due to change in impedances and stimulus delivery
- Change in audibility and/or loudness growth on the affected electrodes
- Possible drop in speech understanding, even with program modifications

What should I do when I observe these symptoms?

We recommend following best programming practices for electrodes with low impedances:

- Adjust threshold and comfort levels for audibility and loudness growth
- Disable electrodes where acceptable audibility and loudness growth are not achieved
- Assess the use of SPAN or disabling the electrode(s) on perception
- Assess sound quality and speech understanding with the program changes

What should I expect if basal electrodes are disabled?

Most commonly, disabling basal electrodes with alter the pitch of familiar sounds

- Frequencies are automatically redistributed among active electrodes
- More stimulation will be directed apically, changing the pitch perception
- Voices or specific phonemes (e.g. /f/, /s/) may sound lower in pitch
- In some cases performance may be affected by the program changes
  - Performance may be improved with improved audibility of high frequency sounds
  - Performance may be diminished when multiple electrodes (e.g. ≥4) are disabled

- Initial sound quality changes due to reprogramming may be overcome with experience

How do I address patient concerns when the issue is not observed or audibility and performance have been addressed by program changes?

- As with all patients, continue to monitor during routine visits and ask them or their caregiver to report any consistent changes in performance to the clinic.
- For pediatrics or patients who are not able to self-report, caregiver should monitor for changes in audibility of high-frequency sounds, specifically phonemes like /f/ and /s/.

How do I address patient concerns when the issue is not resolved with program changes?

- Contact your AB representative for a review and to schedule an integrity test.