

****** Recall Notification******
Advanced Bionics HiRes 90K Cochlear Implant

Dear Cochlear Implant Recipient or Parent,

Our mission at Advanced Bionics is to improve the lives of the hearing impaired, and the safety and well-being of our recipients is our first priority. Because we are committed to ensuring that our products are as safe as possible, we are voluntarily informing you that we have become aware of an issue with the HiRes 90K cochlear implant. The issue can result in pain, overly loud sounds, and/or sudden shock sensation in the implanted ear while the implant is receiving power. Thus far, our investigation shows that of the more than 28,000 implanted HiRes 90K devices, only two explanted devices have been confirmed to have this issue. There are 9 other patients with similar symptoms which our investigations have not yet ruled out as related to this issue. For the two confirmed cases, there were no symptoms upon initial activation of device. However, the patients experienced symptoms after 8-10 days of use. Both recipients were re-implanted with HiRes 90K devices and their clinicians report that they are progressing well.

We are conducting an extensive investigation of this issue using an independent scientific research organization. Their current analysis suggests that, if present, the issue will first occur within 90 days of device use. However, the onset of symptoms may be delayed after initial activation, and they may continue to occur intermittently. In the unlikely event that this symptom occurs, continued device use may lead to damage to the inner ear and/or the auditory nerve. If you or your child experience pain related to implant use, remove the external equipment immediately and contact your cochlear implant clinician to schedule an appointment. If the evaluation of your device identifies this problem, device replacement is advised.

It is important to note that it is not unusual for cochlear implant recipients to experience overly loud sounds. Most of these cases can be resolved with standard troubleshooting, such as the replacement of external equipment. The vast majority of these cases are not signs of the issue described above and do not require explant of the device. We will notify you again as more information from our investigation becomes available.

We sincerely regret any concern this notification may cause. Advanced Bionics assures you that we will correct this issue and continue to improve our product reliability.

If you have any questions regarding this letter, please contact an Advanced Bionics representative at 877-577-4628 (telephone) Monday – Friday 5:00 a.m. – 7:00 p.m. PST or www.advancedbionics.com (live chat) Monday – Friday 5:00 a.m. – 7:00 p.m. PST.

In order to assure the effectiveness of this communication, please complete the enclosed acknowledgment form and return it to us at your earliest convenience by using one of the following options:

E-mail: confirm@advancedbionics.com

Fax: 661-362-7621

Mail: Self-Addressed stamped envelope

Sincerely,

Gerhard Roehrlein, PhD
CTO and Acting CEO