

Q: What cochlear implants are affected by this recall?

A: Only certain unimplanted Advanced Bionics HiResolution 90K cochlear implants with a particular component from Supplier B. No implanted devices are affected by this recall. No explantation of the HiRes90K device is recommended.

Q: Why is this recall taking place?

A: Advanced Bionics has voluntarily recalled certain unimplanted HiRes90K® cochlear implants. These implants may be linked to an elevated risk of moisture-related device failure. We are removing the affected unimplanted devices from hospitals' inventory and replacing them with devices not affected by the recall.

Implants manufactured with a particular component from Supplier A are highly reliable demonstrated by a one-year Cumulative Survival Rate (CSR) greater than 99.5%. A 99.5% CSR means that of every 1000 implanted devices, 995 continue to operate properly at the end of one-year. Devices manufactured with a particular component from Supplier B have a one-year CSR of 97.5%. Because Advanced Bionics is focused on delivering products with the highest quality and reliability, we recalled all implants containing the components from Supplier B.

Q: Will my upcoming cochlear implant surgery be affected by this recall?

A: No. All affected unimplanted devices have been segregated and are being removed from hospitals' inventory. Advanced Bionics assures that all HiRes90K devices manufactured with the particular component from Supplier B are being removed from hospital inventory and are now shipping only devices that had been manufactured by Supplier A. If you have concerns about this or to verify that your surgery can take place as scheduled, we encourage you to contact your cochlear implant surgeon or audiologist.

Q: What are the symptoms of a moisture related device failure?

A: The predominant symptom for implants that experience a moisture-related malfunction is loss of lock (inability for the internal implant to accept communication from the external headpiece) resulting in no sound perception. This is commonly preceded by a period of intermittency (sound going on and off), or the perception of an overly loud sound.

There are other potential reasons for these types of symptoms, including external equipment malfunction (processor, microphone, headpiece, cable); therefore, we recommend that you follow routine troubleshooting procedures and if concerns remain, please consult your implant center.

Q: If I use or my child uses a HiRes90K implant and I have no symptoms, how does this recall affect me?

A: This recall does not affect implanted devices. No action is required on your part.

Q: Did the FDA require Advanced Bionics to issue this recall?

A: No, Advanced Bionics has proactively chosen to issue this HiRes90K recall in our patients' best interest.