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Advanced Bionics initiates corrective action of HiRes Ultra and 3D cochlear implant

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Field corrective action related to the initial version of HiRes Ultra and Ultra 3D cochlear implant devices due to a decrease in performance experienced by a small percentage of recipients

US based Advanced Bionics (AB), a global leader in developing advanced cochlear implant systems, announced today that it has begun notifying regulatory authorities that it will voluntarily initiate a field corrective action related to the initial version of HiRes Ultra and Ultra 3D cochlear implant devices due to a decrease in performance experienced by a small percentage of recipients.

AB's priority is to ensure that all cochlear implant recipients and health care providers have the information they need to understand this situation and that they receive the necessary support. Existing recipients of HiRes Ultra and Ultra 3D may continue to use their device as normal. If recipients experience issues of hearing degradation they should visit their audiologist or other health care provider. In addition, we will begin the notification process for device recipients worldwide, where allowed, to make them aware of the potential issue.

This voluntary action is being taken in an abundance of caution in response to recent increases in Ultra device explants related to low impedances and reports of hearing performance degradation. As of February 11, 2020, of the more than 16,000 recipients of these implants, less than 0.5% have been explanted for this reason. 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.

AB has identified factors that contribute to the clinical symptoms leading to explant and hearing performance degradation. This information will be provided to health care professionals and recipients in geographies that allow. As of February 11th, in the small number of cases that have been explanted,fluid ingress at the electrode has occurred leading to interruption of stimulation. The hermetic seal of the implant case has been shown to be intact.

In our efforts to continually improve our products and in response to early reports of this issue AB has developed several improvements to the device to address the issue (new version). 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 these improvements to additional global regulatory agencies. AB 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 new version of HiRes Ultra and Ultra 3D based on market availability.

Previous generations of AB cochlear implants and external sound processors and accessories are not included in the scope of this voluntary field action.

AB’s primary concern is the safety and hearing performance of our recipients as well as the reliability of our products. AB continues to take all necessary corrective and preventative efforts to address this unforeseen occurrence.