

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE

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FDA

Advanced Bionics Conducts Voluntary Recall of Cochlear Implants *FDA Not Recommending Removal of Implants Already in Place*

The Food and Drug Administration (FDA) announced today that Advanced Bionics Corporation, a wholly owned subsidiary of Boston Scientific Corporation, is conducting a voluntary recall of its un-implanted CLARION and HiResolution cochlear implants because some of the devices may malfunction due to moisture. The firm's recall will include notification to doctors and other healthcare professionals and patients.

Cochlear implants are intended to restore a level of auditory sensation to adults and children with severe-to-profound hearing loss via electrical stimulation of the auditory nerve.

Advanced Bionics has determined that device failure may occur due to moisture inside the product. Symptoms associated with device failure include, but are not limited to: 1) intermittent functioning; 2) sudden sensation of discomfort or pain; 3) sudden loud noise or popping sound; 4) complete loss of sound, and 5) unwillingness of a child to wear his or her external headpiece.

Patients who experience difficulties with these cochlear implants should try the backup cable, headpiece, and then the sound processor. If signs or symptoms persist, the headpiece should be removed and the user should contact his or her hearing care provider.

FDA is not recommending removal or replacement of any devices already implanted in patients. Anyone with questions regarding the content of this recall, should contact Advanced Bionics at 1-877-454-5038, between the hours 5 AM and 5 PM Pacific Time, Monday through Friday. Also, FDA encourages users to report problems with these devices directly to MedWatch, FDA's voluntary reporting program. Reports may be submitted to MedWatch one of four ways: online at: <https://www.accessdata.fda.gov/scripts/medwatch/>; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HFD-410, 5600 Fishers Lane, Rockville, MD 20857.