

3 July 2024

Reference: Follow-up to Boston Scientific Field Action 97178176-FA Communication (Effects Associated with Rechargeable Deep Brain Stimulation (DBS) Implantable Pulse Generator (IPG) Resets)

Dear Physician/Surgeon or Healthcare Professional:

Patient safety is Boston Scientific's highest priority. In April 2024, we communicated information regarding a random and remote potential for therapy to be briefly interrupted (10-15 seconds) due to a system reset during charging of the Vercise Genus™ Deep Brain Stimulation (DBS) Implantable Pulse Generator (IPG). This letter is being provided to update the "Recommendations" section of the April 2024 communication. Although not all DBS patients will be affected by this device behavior, the referenced IPG firmware update will be made available for **any** rechargeable DBS IPGs identified within the advisory communication. This packet contains the following:

1. A copy of the April 2024 Urgent Medical Device Advisory.
2. Patient letter: This letter is available for sharing with your DBS patient and/or to be included within the patient's medical record. The Patient letter can also be accessed on the Boston Scientific Product Advisories page via this link: www.bostonscientific.com/en-US/pprc/product-advisories.html
3. Acknowledgment form: If you have previously completed and returned this form to Boston Scientific, there is no action required; if you have **not** previously completed and returned this form, please follow the enclosed instructions and return the form to Boston Scientific.

Boston Scientific remains committed to continuously improving this important therapy in the interest of patients. Although we recognize the impact this information may have on you and your patients, we believe transparent communication with physicians will ensure you have timely, relevant information for managing your patients and their devices. If you have additional questions, please contact your local Boston Scientific representative.

Sincerely,



Scott Heineman
Vice President, Quality Assurance