Boston Scientific
Neuromodulation

URGENT MEDICAL DEVICE ADVISORY

18 April 2024

To: Physicians/Surgeons, Hospitals, Healthcare Professionals

Subject: Important Medical Device Information – Effects Associated with Rechargeable Deep Brain Stimulation (DBS) Implantable Pulse Generator (IPG) Resets

Reference: Boston Scientific Field Action 97178176-FA

Dear Physician/Surgeon or Healthcare Professional:

Boston Scientific is informing you about the potential for Vercise Genus™ Deep Brain Stimulation (DBS) IPG (Table 1) stimulation therapy to be transiently suspended during charging due to a device reset. This device reset behavior occurs in response to the presence of potential interference during IPG charging. The frequency of occurrence of this IPG reset behavior is random and remote, and patients with devices exhibiting this reset behavior may not report any discernible impact. However, Boston Scientific has received a limited number of patient reports describing a brief return of symptoms during a reset event and/or undesired sensations when stimulation therapy resumes after being transiently suspended. An IPG firmware update is available for patients who experience undesired effects due to this reset behavior. Note that all Vercise Genus DBS IPGs continue to meet required specifications; these devices are operating within established performance thresholds and remain available for implant.

Table 1. Vercise Genus DBS

Material Description	*Material Number*	*GTIN*	*Serial Number Range*	*Expiration Date Range*
VERCISE GENUS R16 IPG KIT	M365DB12160	8714729985044	100209 - 753347	09-OCT-2020 through 26-MAR-2026
VERCISE GENUS R32 IPG KIT	M365DB12320	8714729985051	100104 - 753200	09-OCT-2020 through 21-MAR-2026

Description

Boston Scientific has received reports of undesired sensation and/or transient worsening of movement disorder symptoms secondary to a transient loss of stimulation during IPG charging for patients with rechargeable DBS IPGs. Investigation of these reports

determined that the device may reset (by design) due to detection of noise or interference during IPG charging. When the system resets, the patient's programmed stimulation turns off for approximately 10-15 seconds and then turns back on. When this occurs, some patients may perceive the sudden changes in stimulation. As soon as the reset is complete, the IPG resumes normal operation, including delivery of stimulation therapy.

It is important to emphasize that not every rechargeable DBS IPG will exhibit this device reset behavior during IPG charging, as the frequency of occurrence is random and remote. To date, Boston Scientific has received a total of thirty-two (32) reports of events (an observed occurrence rate of 0.21%) associated with undesired sensations due to DBS IPG resets during charging. There has been one (1) case of intervention/device replacement performed due to undesired sensations. Note that there have been some cases of this behavior with no discernible patient impact. Boston Scientific conservatively includes all reports of unintended IPG resets in risk estimates.

Although a review of field performance data confirms that Vercise Genus DBS IPGs are performing within established product performance expectations and continue to meet the intended use with respect to safety and performance, Boston Scientific has identified improvements (including an IPG firmware update for implanted devices) that will prevent this device reset behavior from occurring during IPG charging. Updating the IPG firmware eliminates the possibility of a coincident routine system check during IPG charging, thus preventing a potential system reset. Boston Scientific field representatives can install this firmware update on implanted IPGs for patients who have experienced undesirable sensations during IPG charging due to this device reset behavior.

Clinical Impact

As noted previously, DBS patients with devices that exhibit IPG resets during charging may experience undesired sensations (i.e., paresthesias), transient worsening of movement disorder symptoms (i.e., tremors) or no discernible clinical effects due to a transient loss of stimulation. Although there have been no long-term patient consequences reported to date, the potential exists for clinical impact. Those foreseeable effects may include transient patient symptoms; undesired sensations when stimulation therapy turns off for approximately 10-15 seconds, then turns back on; and/or additional surgical intervention for removal (i.e., if a patient requests a replacement or revision due to these effects).

Recommendations

While the observed field performance for Vercise Genus rechargeable DBS IPGs is within established limits, an IPG firmware update is available for patients who have experienced effects related to this device reset behavior during IPG charging.

1. Review any patient reports of undesired sensations indicative of potential device reset behavior during IPG charging and report these observations accordingly to Boston Scientific.

2. After Boston Scientific verifies this device reset behavior has occurred during IPG charging, an in-field IPG firmware update can be scheduled for the patient's device. This will eliminate the possibility of a coincident routine device system

check during IPG charging, thus preventing a potential system reset. Append the patient's medical record accordingly if a firmware update has been completed.

Additional Information
Complete the attached, mandatory Acknowledgment Form and return it to Boston Scientific promptly (please refer to the enclosed instructions). Any adverse events or quality concerns associated with use of this product should be reported to Boston Scientific via email at BSN.ComplaintCallCenter@bsci.com or FDA's MedWatch Adverse Event Reporting program [www.fda.gov/MedWatch/report.htm or 1.800.FDA.1088 (332.1088)].

Patient safety is our highest priority. As such, we are committed to transparent communication to ensure that you have timely, relevant information for managing your patients. If you require additional assistance or more information regarding this communication, please contact your local Boston Scientific representative.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance
Boston Scientific

Urgent Medical Device Advisory - Instructions

The Acknowledgment Form enclosed with this notification must be completed and returned to Boston Scientific. **No product is being recalled and you are not required to return product to Boston Scientific.**

1. Immediately post this information in a visible location near the product(s) to ensure information is easily accessible to all users.
2. Complete and return the Acknowledgment Form to the Boston Scientific Field Action Center:

Email:	BSCFieldActionCenter@bsci.com; OR
Fax:	Field Action Center 1-866-213-1806