

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country»

<Reference: 97178176-FA>

18 April 2024

Urgent Field Safety Notice

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

Dear «Users_Name»,

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.

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

Instructions:

- Immediately post this information in a visible location near the product(s) to ensure information is easily accessible to all users.
- No product is being recalled and you are not required to return product to Boston Scientific.
- Please **complete the enclosed Acknowledgment Form** and **send it to Boston Scientific at «Customer_Service_Fax_Number» by 13 May 2024.**
A completed form is required from every facility who receives this letter.
- Any adverse events or quality concerns associated with use of this product should be reported to Boston Scientific.

Additional Information:

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

Attachment: Acknowledgment Form



Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country»

Acknowledgement Form – Urgent Field Safety Notice
Effects Associated with Rechargeable Deep Brain Stimulation (DBS)
Implantable Pulse Generator (IPG) Resets

97178176-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 18 April 2024 for

Effects Associated with Rechargeable Deep Brain Stimulation (DBS)
Implantable Pulse Generator (IPG) Resets

NAME* _____ **Title** _____

Telephone _____ **Email** _____

SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy