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<Reference: 97222956-FA> 8 August 2024

Urgent Field Safety Notice

Subject: Submuscular Implantation of Vercise Genus™ Deep Brain Stimulation (DBS) Implantable Pulse Generators (IPGs) with Feedthrough (FT) Wire Break(s)

Dear «Users_Name»,

Boston Scientific is writing to remind you to follow the steps outlined in the labeling/Instructions for Use (IFU) to implant Vercise Genus Deep Brain Stimulation (DBS) Implantable Pulse Generators (IPGs) within a subcutaneous pocket. Device header feedthrough (FT) wire break(s) have occurred only in rechargeable Vercise Genus DBS IPGs (as detailed in the table 1 below) that were implanted submuscular in the pectoral location. Per device labeling/IFU, the Vercise Genus DBS IPG is intended to be implanted in a subcutaneous pocket. Boston Scientific has not received reports of FT wire breaks with Vercise Genus DBS IPGs implanted in a subcutaneous pocket. The Vercise Genus DBS rechargeable IPG continues to meet safety and performance expectations when used in accordance with device labeling.

Table 1:

Material Description	Material Number	GTIN	Serial Number
VERCISE GENUS R16 IPG KIT	M365DB12160	8714729985044	All
VERCISE GENUS R32 IPG KIT	M365DB12320	8714729985051	All

Description:
To date, Boston Scientific has received a total of ten (10) similar events worldwide involving high monopolar impedances with rechargeable Vercise Genus DBS IPGs. The patients also reported experiencing return of their pre-implant symptoms (e.g., tremor, immobility, bradykinesia, rigidity, slow speech and/or difficulty walking). Seven (7) of these events occurred at one facility, whereas

the other three (3) events occurred at separate facilities (with a worldwide occurrence rate of 0.06% of all products sold). Eight (8) devices were returned to Boston Scientific for laboratory analysis; each of the returned devices exhibited device header FT wire break(s) with evidence of flex fatigue. All events involved a submuscular device implant location.

The root cause investigation for the FT wire breaks has determined that the use of a submuscular implant technique in the pectoral region can lead to additional, frequent muscle tension forces on an IPG against the patient's ribs, especially if the device is sutured to the muscle, ultimately resulting in device header FT wire break(s). These repetitive stresses are not applicable for an IPG implanted in a subcutaneous pocket, per device labeling.

The existing device labeling/Instructions for Use (IFU) specify placement of the IPG within a subcutaneous pocket. Boston Scientific does not have testing data to support implanting Vercise Genus DBS IPGs in other locations not specified within device labeling/IFU.

Clinical Impact:

Complete or partial breaks of device header FT wire(s) will prevent successful delivery of stimulation therapy, thus requiring removal/replacement of the device. Clinical observations of high monopolar impedances, undesired sensation, sudden loss of therapy, return of pre-implant symptoms and/or Bluetooth connectivity challenges may be potential signals associated with FT wire break(s). Each of the ten (10) reports received to date were associated with high monopolar impedances, most of which were accompanied by a return of the patient's pre-implant symptoms. Note that there have been no associated long-term patient consequences reported with these events.

Recommendations:

- ***When implanting Vercise Genus DBS IPGs****:*
  Follow existing device labeling/IFU regarding implant location within a subcutaneous pocket.

- ***For any patient with a rechargeable Vercise Genus DBS IPG implanted submuscular in the pectoral region:***
  A patient letter is available to Healthcare Professional on demand which can be shared with the patient and/or included within the patient's medical record. Monitor per relevant IFU recommendations for any clinical observations of high monopolar impedances, undesired sensation, sudden loss of therapy, return of pre-implant symptoms and/or Bluetooth connectivity challenges, as these may be signals of potential FT wire break(s).

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 29 August 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:

Your Competent Authority is being notified of this Field Safety Notice.

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,

Scott Heineman
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

Submuscular Implantation of Vercise Genus™ Deep Brain Stimulation (DBS) Implantable Pulse Generators (IPGs) with Feedthrough (FT) Wire Break(s)

97222956-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 8 August 2024 for

Submuscular Implantation of Vercise Genus™ Deep Brain Stimulation (DBS) Implantable Pulse Generators (IPGs) with Feedthrough (FT) Wire Break(s)

NAME* _____ Title _____

Telephone _____ Email _____

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