

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country»

<Reference: 97178176B-FA>

17 July 2024

Urgent Field Safety Notice

Subject: Important Medical Device Information – Effects Associated with Rechargeable Spinal Cord Stimulation (SCS) Implantable Pulse Generator (IPG) Resets.

Dear «Users_Name»,

Boston Scientific is informing you about the potential for WaveWriter Alpha™ Spinal Cord Stimulation (SCS) 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 the awareness of IPG turning off and on during a reset event and/or undesired sensations when stimulation therapy resumes after being transiently suspended. An IPG firmware update is available to prevent this reset behavior from occurring during device charging. Note that all WaveWriter Alpha SCS IPGs continue to meet required specifications; these devices are operating within established performance thresholds and remain available for implant.

Table 1: WaveWriter Alpha SCS

Material Description	Material Number	GTIN	Serial Number Range
WAVEWRITER ALPHA 16 IPG KIT	M365SC12160	8714729985082	100188 - 758920
WAVEWRITER ALPHA 32 IPG KIT	M365SC12320	8714729985099	100635 - 759404

Description:

Boston Scientific has received reports of undesired sensation and/or awareness of IPG turning off and on during IPG charging for patients with rechargeable SCS 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 SCS IPG will exhibit this device reset behavior during IPG charging, as the frequency of occurrence is random and remote. At the time of the analysis, Boston Scientific had received a total of two (2) reports of events (an observed occurrence rate of 0.003%) associated with undesired sensations due to SCS IPG resets during charging. Four (4) other patients reported that their stimulation seemed to 'turn off and on by itself' but did not note any other impact. Note that there have been some cases of this behavior with no discernable effects. Additionally, there have been four (4) cases of intervention/device replacement; however, it was unclear whether these cases were related to the device reset behavior. Boston Scientific conservatively includes all reports of unintended IPG resets in risk estimates.

Although a review of field performance data confirms that WaveWriter Alpha SCS 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. This firmware update is available for any rechargeable SCS IPGs identified within this advisory communication.

Clinical Impact:

As noted previously, SCS patients with devices that exhibit IPG resets during charging may experience undesired sensations, awareness of IPG turning off and on, or no discernible clinical effects due to a transient loss of stimulation therapy. Although there have been no long-term patient consequences reported to date, the potential exists for clinical impact. Those foreseeable effects may include awareness of stimulation turning off and on; 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 WaveWriter Alpha rechargeable SCS IPGs is within established limits, an IPG firmware update is available for patients to eliminate the possibility of this device reset behavior occurring during IPG charging.

- Review any patient reports of undesired sensations indicative of potential device reset behavior during IPG charging and report these observations to Boston Scientific.
- An in-field IPG firmware update is available through an in-clinic visit 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 is 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 9 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

Effects Associated with Rechargeable Spinal Cord Stimulation (SCS) Implantable Pulse Generator (IPG) Resets

97178176B-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 17 July 2024 for

Effects Associated with Rechargeable Spinal Cord Stimulation (SCS) Implantable
Pulse Generator (IPG) Resets.

NAME* _____ Title _____

Telephone _____ Email _____

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