



URGENT MEDICAL DEVICE ADVISORY

17 July 2024

To: Physicians/Surgeons, Hospitals, Healthcare Professionals

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

Reference: Boston Scientific Field Action 97178176B-FA

Dear Physician/Surgeon or Healthcare Professional:

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

<i>Material Description</i>	<i>Material Number</i>	<i>GTIN</i>	<i>Serial Number Range</i>
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.

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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.

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

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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](tel:1800FDA1088) (332.1088)].

Patient letter is enclosed with this communication. This letter is provided for sharing with your 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.

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
Boston Scientific

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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