URGENT MEDICAL DEVICE CORRECTION

Proclaim™ Implantable Pulse Generator
Model Numbers 3660, 3661, 3662, 3363
UDI 05415067031419, 05415067020208, 05415067031426, 05415067020239
Proclaim™ Plus Implantable Pulse Generator
Model Numbers 3670, 3671, 3672, 3673
UDI 05415067046383, 05415067046390, 05415067046406, 05415067046376
Proclaim™ Implantable Pulse Generator (DRG)
Model Number 3664 UDI 05415067020215

Neuromodulation
Abbott Medical
6901 Preston Road
Plano, TX 75024
USA

April 2026

Dear Physician,

Abbott is sharing important information regarding the Proclaim™ Spinal Cord Stimulation (SCS) and Proclaim™ Dorsal Root Ganglion (DRG) Neurostimulation Systems. The purpose of this communication is to remind health care providers that these systems contain a Surgery Mode feature designed to help protect the implanted device from potential interference associated with the use of electrosurgical units (ESUs) during certain surgical procedures.

What you need to know

The Proclaim SCS and DRG Neurostimulation Systems continue to operate as intended and deliver therapy safely. There have been no changes to the known risks associated with ESU use. Physicians are reminded to reiterate with patients, consistent with the Instructions for Use (IFU), that exposure to electrosurgery during certain surgical procedures may pose a risk of device interference and potential loss of therapy if appropriate safety measures are not followed.

The Proclaim SCS and DRG Neurostimulation Systems Surgery Mode feature, available since 2017, is designed to help protect the device from damage associated with ESU use. Prior to any surgical procedure, Surgery Mode must be enabled using a Patient Controller (PC) or a Clinician Programmer (CP). Failure to enable Surgery Mode may result in device damage and additional surgery may be required to replace the Implantable Pulse Generator (IPG) to restore therapy. In 2025, the rate of additional surgery was 0.55% for SCS and 0.24% for DRG, which is consistent with rates observed over the past several years since the introduction of Surgery Mode.

Additionally, it is important to understand that the level of risk and available mitigation options vary across systems within the Abbott Pain Therapy portfolio.

- For Proclaim systems, Surgery Mode must be manually enabled using the PC or CP prior to surgery involving ESUs.
- For Eterna systems (IPG Model 32400), Surgery Mode should be manually enabled. However, Surgery Mode will automatically activate if high current from an ESU is detected, providing an additional layer of protection to help reduce the risk of IPG damage during surgery.

The majority of reported events occurred during subsequent surgical procedures unrelated to SCS or DRG therapy management in which Surgery Mode was not enabled. No patient harm has been reported beyond the need for additional surgery to restore therapy. It is important to note that, even when Surgery Mode is enabled, the IPG may still be susceptible to damage if ESU warnings outlined in the Clinician IFU are not followed. The risk of device damage is significantly reduced by following the IFU and the guidance provided in this communication.

Patient Management Recommendations

Abbott recommends that physicians educate patients on the following points, consistent with the IFU (in either the *Using the Surgery Mode Feature* or the *Setting Your Generator to Surgery Mode* sections), to emphasize the importance of using Surgery Mode.

- Prior to any surgical procedure, ensure that the device is placed in Surgery Mode using a PC or CP.
  If needed, patients may be directed to https://abbo.tt/surgerymodeCPT for instructions on how to place the device in Surgery Mode.

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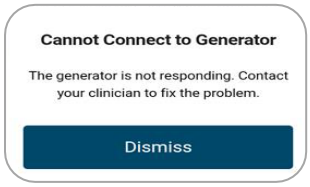
- Remind patients to present their Abbott Patient Identification Card to their surgical care team prior to the procedure. This card contains information about the implanted IPG and can be used to help surgeons identify the appropriate device IFU(s) and review relevant ESU-related precautions and warnings.
- Discuss the level of risk and available Surgery Mode mitigation options within the Abbott Pain Therapy portfolio systems with your current and prospective patients when making device selection decisions.

Surgery Related Electrosurgery Considerations

- Post surgery, if patient's PC displays the following message, connect with a CP to determine whether the issue can be resolved.



- In accordance with the IFU, the following precautions should be observed to help avoid patient injury or damage to the neurostimulation system, even when Surgery Mode is enabled:
  - Use bipolar electrosurgery only.
  - Keep the ESU current paths as far from the neurostimulation system as possible.
  - Set the electrosurgery device to the lowest possible energy setting.
  - Refer to the Clinician IPG IFU, Electrosurgery section, available on https://manuals.eifu.abbott.

For questions regarding this communication, please contact your Abbott representative, or Abbott Technical Support at 1-800-727-7846.

Please return a completed Acknowledgement Form and retain a copy of both this notice and the completed Acknowledgement Form for your records. Additionally, please share this information with others at your institution who participate in patient management by directing them to this letter, which is also available on https://www.neuromodulation.abbott/us/en/product-advisories.html.

Adverse events or quality issues associated with the use of this product may also be sent to the FDA through Medwatch, the FDA Safety Information and Adverse Event reporting program, by submitting Form FDA 3500 online at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program, by calling 1-800-FDA-1088, or by faxing 1-800-FDA-0178.

Abbott remains committed to delivering high-quality products and responsive support. We apologize for any inconvenience this communication may cause and appreciate your continued partnership in supporting patient safety and satisfaction.

Sincerely,

Christopher Longpre
Divisional Vice President, Quality
Neuromodulation
Abbott