URGENT MEDICAL DEVICE CORRECTION

Infinity™ Implantable Pulse Generator
Model Number 6660, 6661, 6662, 6663
UDI 05415067030016, 05415067020246, 05415067020253,
05415067030023, 05415067020260, 05415067020277

Neuromodulation
Abbott Medical
6901 Preston Road
Plano TX 75024
USA

April 2026

Dear Patient,

Abbott is sharing important information regarding your Infinity™ Deep Brain Stimulation (DBS) System. The purpose of this communication is to remind you that your system contains a Surgery Mode feature. When enabled, this existing feature is designed to help protect your implanted device from damage which may occur during surgery.

What you need to know

Your Infinity DBS system continues to operate as intended and deliver therapy safely. There are no new or increased risks related to device damage when certain surgical tools are used. If you are going to undergo surgery, it is important that you are aware of the following:

- Surgery Mode can be turned on using your Patient Controller (PC) or by your Abbott representative or physician using the Clinician Programmer (CP).
- Exposure to certain surgical equipment may damage your implanted device.
- To reduce the risk of damage, Surgery Mode must be turned on before any surgery.
- If the device is not placed in Surgery Mode and is damaged in surgery, an additional surgery may be required to replace your device to restore therapy. In 2025, the rate of additional surgery was 0.13% for DBS, which is consistent with rates observed over the past several years since the introduction of Surgery Mode.

The majority of reported events occurred during subsequent surgical procedures unrelated to DBS therapy management where 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 device may still be susceptible to damage if Electrosurgery warnings outlined in the Clinician Instructions for Use are not followed. The risk of device damage is significantly reduced by following the instructions in your user Instructions for Use and guidance in this communication.

What you need to do

Follow the guidance currently available in your Instructions for Use (in either the *Using the Surgery Mode Feature* or the *Setting Your Generator to Surgery Mode* sections), if you are going to undergo surgery:

- Prior to any surgery, place the device in Surgery Mode using your Patient Controller. Using this feature also turns stimulation off while you undergo your procedure. For instructions on how to enable Surgery Mode, refer to https://abbo.tt/surgerymodeDBS website.

- Provide your Abbott Patient Identification Card to your surgical care team before the surgery.
  - The identification card contains information about your implanted device and can help your surgical team identify the appropriate device Instructions for Use and review relevant Electrosurgery-related precautions and warnings (in the *Warnings* section of the Instructions for Use).

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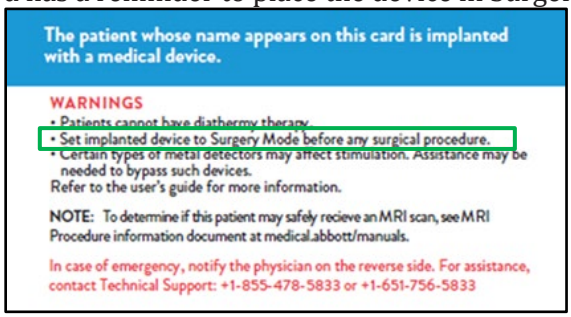
- The identification card has a reminder to place the device in Surgery Mode.

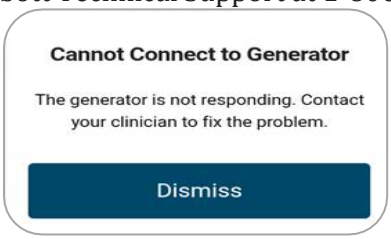


The above image is an example representation of the Patient Identification Card. Specific card will vary by device model.

- If you need to request a replacement card, contact Abbott Technical Support at 1-800-727-7846, Option 2.

- After your surgery, disable Surgery Mode to restart stimulation. For instructions on how to disable Surgery Mode, refer to the https://abbo.tt/surgerymodeDBS website.

- Post surgery, if your PC displays the following message or if you have any further questions, contact your Abbott representative or Abbott Technical Support at 1-800-727-7846, Option 3.



A copy of this letter is available on https://www.neuromodulation.abbott/us/en/product-advisories.html.

Adverse events or quality problems experienced with the use of this product may 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 faxing 1-800-FDA-0178.

Abbott remains committed to delivering high-quality products and responsive support. Thank you for your understanding; we apologize for any inconvenience this communication may have caused.

Sincerely,

Christopher Longpre
Divisional Vice President, Quality
Neuromodulation
Abbott