



## Important Medical Device Advisory

### Dear Abbott Patient:

Our records indicate that you have a St. Jude Medical, an Abbott Laboratories company, device implanted. Abbott has recently announced a medical device advisory for our company's Proclaim Elite™ and Infinity™ devices to notify our patients and physicians that a small number of patients have had a loss of therapy during surgical procedures due to interactions with other surgical equipment. The likelihood that this will impact your health is low. Should you require a future surgery, a solution to improve your device's protection called "Surgery Mode" is now available in a software upgrade and should be enabled prior to any future surgery. It is important to note, "Surgery Mode" does not completely eliminate the risk of an IPG becoming non-responsive. If therapy is lost, "Surgery Mode" may restore therapy to the user. Otherwise, replacement surgery is required. Please read the details below.

**It is important for you to understand that your device is functioning normally. If you plan to have a surgery please ensure the below steps are followed prior to your surgery. An Abbott Support number has been set up to assist you with these steps at 1-888-397-8828. (U.S.).**

### These are the steps to receive your software upgrade:

- 1. Install updated software.** Please download the available software upgrade. After the update completes, you will see a Notification screen that describes "Surgery Mode."
- 2. Connect your device to a Clinician Programmer.** In order to activate the "Surgery Mode" feature, a one-time connection to a Clinician Programmer is needed at your next checkup. Please schedule an appointment for follow-up if you plan on having a surgical procedure, or ensure this update is completed prior to that procedure. The Abbott Support number can assist you with these steps at 1-888-397-8828 (U.S.).
- 3. Follow the Instructions For Use for "Surgery Mode" prior to a surgical procedure.** A brochure is enclosed which outlines the steps to use this feature. Instructions can also be found at [manuals.sjm.com](http://manuals.sjm.com).

A website has been set up to provide you with information on this advisory:

[sjm.com/SurgeryModeUpdate](http://sjm.com/SurgeryModeUpdate)

If you have any questions, please contact your Abbott Technical Support at **1-888-397-8828 (U.S.)**. We sincerely apologize for any difficulties this current issue causes you or your caregivers. We take this matter very seriously. Please know that we are available to assist you if you are having problems with your device.

Sincerely,

A handwritten signature in black ink that reads 'SJSlane'.

Susan Jezior Slane  
Divisional Vice President, Quality Assurance and Compliance  
Abbott Cardiovascular and Neuromodulation