URGENT MEDICAL DEVICE CORRECTION

Neuromodulation
Abbott Medical
6901 Preston Road
Plano TX 75024
USA

Proclaim™ XR SCS System and Proclaim™ Elite SCS System
(Model Numbers 3660, 3662)
UDI 05415067031419, 05415067031426, 05415067020192, 05415067020222
Proclaim™ Plus SCS System (Model Numbers 3670, 3672)
UDI 05415067046383, 05415067046406
Proclaim™ DRG Neurostimulation System (Model Number 3664)
UDI 05415067020215

October 2023

Dear Patient,

This letter is to notify you about important information regarding your Proclaim™ Neurostimulation System, should your physician determine that you need a future Magnetic Resonance Imaging (MRI) scan. Your patient controller includes a feature called MRI mode which allows you and your device to be safely scanned.

The scope of this correction is related to the inability to exit MRI mode in specific situations. If additional troubleshooting steps are unsuccessful, the implanted device would be unable to exit MRI mode and resume normal operation. This would require device replacement surgery to restore therapy. If you are using MRI mode, there are steps you should take to avoid this issue.

WHAT YOU NEED TO KNOW

Your Proclaim™ implantable pulse generator (IPG) will still safely deliver therapy, and this issue does not change your ability to receive an MRI scan as determined by your physician. MRI mode is intended to protect you and your device during an MRI scan. Before any MRI, your Patient Controller should be used to enter MRI mode. After your MRI, your Patient Controller should be used to exit MRI Mode.

In some instances, IPGs are unable to exit MRI mode if:
- Patient Controller is lost or damaged while your implant is in MRI mode
- Patient Controller is locked (e.g., forgotten Apple password) while your implant is in MRI mode
- Patient Controller application and/or iOS‡ software is updated while your implant is in MRI mode
- Bluetooth® connection with the IPG is deleted from the list of available Bluetooth® devices on the Patient Controller while it is in MRI mode

In these instances, if troubleshooting steps are unsuccessful, an additional surgery would be required to replace the IPG to restore therapy. Between August 2015 and August 2023, there have been 75 occurrences worldwide where patients needed additional neurostimulator replacement surgery to restore therapy. This issue can be avoided by following the instructions in your patient manual and guidance in this communication.

WHAT YOU NEED TO DO

Following the guidance currently available in the Instructions for Use and your patient manual, if you need to receive an MRI scan:

- Contact your clinician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks.
- Before attempting to place your device into MRI mode and with the help of your physician or Abbott representative, ensure your Patient Controller app is updated to the latest *"Patient Controller NR - US"* application from the Apple‡ App Store‡.
- Disable automatic updates for the Patient Controller app and iOS‡ software before placing the IPG in MRI mode
- Set your implant to MRI mode within a day prior to arrival for your procedure.
- Do not alter, damage, update or lose your Patient Controller handheld while your implant is in MRI mode.
- Do not update, install, or delete Patient Controller app or Bluetooth® connection while your implant is in MRI mode.
- After MRI scan, use your Patient Controller to exit MRI mode which will turn stimulation on and restore therapy.

This information is also available on the Abbott Neuromodulation System website at manuals.sjm.com and MRIwithAbbott.com

If you are unable to use your Patient Controller to communicate with your implant while in MRI mode, contact your physician, Abbott representative, or Abbott Technical Support at 1-800-314-0940 immediately, as there may be additional troubleshooting steps to restore communication with your neurostimulator implant and exit MRI mode.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online
- Call 1-800-FDA-1088 to report by telephone
- Download form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages – do not send instruction pages).

Abbott is committed to providing the highest quality products and support. Thank you for your understanding; we apologize for any inconvenience this issue may have caused.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality
Abbott Neuromodulation