Neuromodulation
Abbott
6901 Preston Rd.
Plano, TX 75024 USA

URGENT MEDICAL DEVICE CORRECTION

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

Infinity™ DBS System (Model Numbers 6660, 6662)
UDI 05415067030016, 05415067030023

July 2023

Dear Doctor,

Abbott is sharing important information about the use of Proclaim™ XR SCS System, Proclaim™ Elite SCS System, Proclaim™ Plus SCS System, Proclaim™ DRG Neurostimulation System and Infinity™ DBS Systems. The purpose of this communication is to remind health care providers about the use of the magnetic resonance imaging (MRI) mode feature on these systems and the associated risks related to inability to exit MRI mode, including the potential need for implantable pulse generator (IPG) replacement surgery to restore therapy.

During standard use, a Bluetooth® paired Patient Controller is used to place a patient's implantable pulse generator in MRI mode, which in turn disables the delivery of therapy. Upon completion of the MRI, the paired Patient Controller is then used to exit MRI mode and allow therapy to resume.

Abbott has received complaints from patients who are unable to exit MRI mode, as their Patient Controller has lost the ability to connect or communicate with their IPG while in MRI mode. Situations where this has occurred include where the user deleted the Bluetooth® pairing, lost or disabled their Patient Controller, or upgraded the iOS‡ software on their Patient Controller while in MRI mode.

A Clinician Programmer is required to be paired to the IPG for initial programming. When available, a Clinician Programmer previously paired with the patient's IPG can be used to exit MRI mode. If there is no previously paired Clinician Programmer available, this will result in the inability to exit MRI mode. In these instances, an additional surgery would be required to replace the IPG to restore therapy. The overall worldwide occurrence rate of this issue is 0.06%; 0.03% have resulted in loss of therapy and additional surgery to date. Based on these occurrences, Abbott previously updated the Patient Controller Instructions for Use and Patient Controller application MRI mode screen to remind the patient to not delete the paired Bluetooth® connection between their IPG and the Patient Controller.

Next Steps

Per Abbott's Instructions for Use, patients are advised to contact their physician before having an MRI to discuss all critical information regarding MRI scans and MRI mode. In alignment with the Clinician Programmer and Patient Controller Instructions for Use, Abbott recommends physicians do the following to reduce risk of loss of therapy and the need for IPG replacement surgery to restore therapy:

- ***For the Patient Controller,*** advise the patient not to delete the paired Bluetooth® connection between their IPG and the Patient Controller and not to alter, damage or lose their Patient Controller while the IPG is in MRI mode.
- ***For the Patient Controller prior to entering MRI mode,*** ensure patients have upgraded their Patient Controller to the latest ***"Patient Controller NR - US"*** application from the Apple‡ App Store‡. This version of the application provides instructions for the user not to delete the IPG pairing while the system is in MRI mode.
- ***For the Clinician Programmer,*** maintain the paired Bluetooth® connection between the IPG and the Clinician Programmer by avoiding deleting the pairing and disabling automatic iOS‡ software upgrades from the iOS‡ settings.
- ***For questions about this issue or to report patients who are unable to exit MRI mode,*** please contact your local Abbott representative or Abbott Technical Support at 1-800-727-7846 (option 3) for assistance.

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

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 the 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 the instruction pages.)

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this may cause you and your patients, and we appreciate your support in ensuring patient safety and customer satisfaction.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality
Neuromodulation
Abbott

Abbott