



Update to 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

Infinity™ DBS System (Model Numbers 6660, 6662)

UDI 05415067030016, 05415067030023

July 2025

Dear Doctor,

Abbott is providing this **informational update** as a follow-up to a previously issued communication regarding potential risk of patients being unable to exit magnetic resonance imaging (MRI) mode while using Abbott Proclaim™ and Infinity™ IPGs. **No new action is required from you at this time.** You can access the original communication at https://www.neuromodulation.abbott/content/dam/nm/neuromodulation/downloadables/AttachmentF_USLetterv3_updatedJul182023.pdf

To address this issue, Abbott has implemented the following two solutions:

For currently implanted Proclaim™ and Infinity™ IPGs that are unable to exit MRI mode, because paired Patient Controller (PC) or Clinician Programmer (CP) is unavailable, Abbott has developed an external handheld tool. This tool wirelessly disables MRI Mode, enabling unpaired Patient Controllers (PCs) and Clinician Programmers (CPs) to establish connection with the IPG. To request the tool please contact your Abbott Representative or Abbott Technical Support at 1-800-727-7846.

For newly implanted patients, the latest commercially released versions of Proclaim™ and Infinity™ IPGs now support pairing with a PC or CP while in MRI mode. This allows IPGs to exit from MRI mode, even when previously paired PC and CP are unavailable. For pairing instructions, refer to the Instructions for Use (IFU) for PC App Models 3875, 3876 and CP App Model 3874, available at www.eifu.abbott

The activities described above demonstrate Abbott's commitment to quality and our dedication to the patients we serve. We appreciate your continued partnership. For further inquiries, please call your Abbott Representative or Abbott Technical Support.

Sincerely,

Christopher Longpre
Divisional Vice President, Quality
Neuromodulation
Abbott