IMPORTANT MEDICAL DEVICE CORRECTION

FOR A SUBSET OF ELLIPSE™ IMPLANTABLE
CARDIOVERTER DEFIBRILLATORS
MODEL: CD2411-36C
GTIN: 05414734507585

January 22, 2020

Dear Physician,

Abbott is notifying physicians that a small number of Ellipse™ Implantable Cardioverter Defibrillators (ICDs) may lose wireless radiofrequency (RF) communication. A total of 41 devices in the United States are affected. Devices will continue to function normally, but remote monitoring and data transmission capabilities may be interrupted. There have been no reports of patient injury occurring as a result of this issue.

Abbott records indicate you are following one or more patients implanted with an affected device, as noted in the enclosed acknowledgement form.

Background

In April 2018 Abbott released cybersecurity updates to the Merlin™ Patient Care System (PCS) Programmer and Merlin@home™ Transmitters. In a small subset of devices that received those updates patients can no longer be interrogated with wireless RF telemetry or monitored remotely. Investigation has determined that an RF authentication parameter limited to these 41 devices is incompatible with the cybersecurity update. No other Ellipse™ devices are affected by this issue.

Patient Management Recommendations

Abbott has developed a software patch for the Merlin™ PCS Programmer which restores wireless RF communication capability in affected devices. This solution does not present additional risk to patients and device explant is not required for the update. The solution is available in Merlin™ PCS Programmer software Model 3330 v24.6.1 and Abbott will assist in updating programmer software and restoring wireless RF communication for these devices.

We recommend working with your Abbott representative to help correct affected devices during the patient's next regularly scheduled visit.

Please return a completed Acknowledgement Form and maintain a record of this notice along with a copy of the completed Acknowledgement Form to ensure effectiveness of this communication.

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.

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 understanding as we act to ensure patient safety and customer satisfaction. If you have any questions about this communication or the patient management recommendations, please contact your Abbott representative or Abbott Technical Support at **1-800-722-3774 (U.S.).**

Sincerely,

B. Blunt.

Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management