Medtronic
Surgical Innovations
Covidien LLC (Medtronic Company)
200 Medtronic Drive,
Lafayette, CO 80026

www.medtronic.com

URGENT: MEDICAL DEVICE CORRECTION

Valleylab™ FT10 FT Series Energy Platform

Model # VLFT10GEN

November 2023

[redacted]

Dear Health Care Providers:

The purpose of this letter is to inform you of an update of the software running on the Valleylab™ FT10 Energy Platform to version 4.0.4. This software update serves as a correction applicable to all Valleylab™ FT10 Energy Platforms running software versions 4.0.1, 4.0.2, and 4.0.3. The software update is available through the Medtronic Valleylab™ Exchange (VLEx) and through your Medtronic sales or service representatives. Note that software version 4.0.4 is available for update to all Valleylab™ FT10 Energy Platforms, regardless of current software version.

Issue Description:

As a part of the investigation into this issue, it was noted that upon insertion of a new (unused) LigaSure™ device, the Valleylab™ FT10 Energy Platform running software versions 4.0.1, 4.0.2 and 4.0.3 may erroneously indicate that the LigaSure™ device was used previously. When this occurs, the energy platform will display error "E420 Usage Limit" or error "E416 Unknown Instrument," and the LigaSure™ device would not be allowed to be used. Through 07-November-2023, there have been 113 complaints for this issue. Upgrading the Valleylab™ FT10 Energy Platform to the newly released software version 4.0.4 will eliminate this issue.

Potential Health Hazard:

No patient harm has been reported in relation to this voluntary Medical Device Correction. The anticipated patient harm is delay of treatment. There is no impact on patients who have previously undergone a procedure using the energy platform. These patients should continue to be monitored per your practice's normal follow-up procedures.

Product Scope:

Product Name	Model Number	Serial Number
Valleylab™ FT10 FT Series Energy Platform	VLFT10GEN	All Serial Numbers running software versions 4.0.1, 4.0.2 and 4.0.3.

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Actions to be taken:

- Immediately notify all personnel in all care environments in which the Valleylab™ FT10 Energy Platform is used about this Medical Device Correction notice.
- Update Valleylab™ FT10 Energy Platform to software version 4.0.4 to eliminate this issue.
    - For customers already familiar with the software update process through VLEx, software may be directly updated.
    - For customers not familiar with the software update process through VLEx, your Medtronic representative will assist in updating your Valleylab™ FT10 Energy Platform to software version 4.0.4. Your Medtronic representatives will schedule servicing to update the software within the coming weeks.
- Until the software is updated, the Valleylab™ FT10 Energy Platform and LigaSure™ devices can continue to be used as instructed in the User Guide and per your facility protocols. However, please note that the error messages precluding use of LigaSure™ devices may be encountered until software version 4.0.4 is installed.
- Complete the attached Customer Confirmation Form and return it as directed to confirm your receipt and understanding of this information.
- If you are aware of any incidents related to this issue, please contact the Medtronic Service Experience immediately at 800-255 8522 to provide information regarding those events.

Additional Information:

Medtronic will notify all applicable regulatory agencies and competent authorities about this matter.

Adverse events or quality problems experienced with this product should be reported to Medtronic and to the FDA MedWatch Adverse Event Reporting program via:

- The FDA website at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
- FDA telephone at 1-800-FDA-1088
- Call Medtronic Quality Assurance at 800 255 8522 (US Toll free)

Medtronic regrets any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

Bryan Dannettell
VP Quality, Surgical
SURGICAL INNOVATIONS QLTY MG