Medtronic

Urgent Field Safety Notice

Defibrillators

Return for engineering evaluation

TBD April 2024

Medtronic Reference: FA1416

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000019977>

Dear Account Manager/Healthcare Professional,

Medtronic is retrieving the device(s) listed below from your inventory. Your Medtronic representative will collect the device(s) and arrange for/provide a replacement device(s).

- Cobalt™ XT DR Cardiac Resynchronization Therapy Defibrillator serial # **ABCD123456**
- Evera™ XT DR Defibrillator serial # **ABCD123456**

Medtronic's internal review processes identified that this device(s) may have undergone a specific manufacturing sequence that requires additional engineering evaluation. No other products in your inventory are being retrieved for this evaluation.

No immediate risk to patients has been identified. In the unlikely event that a patient has received one of the identified device(s), there are no recommended changes to the standard follow-up care protocol.

Please acknowledge receipt of this letter by signing below. No other action is required.

If you have questions regarding this communication, please contact your Medtronic representative. Thank you for your attention to this matter,

Local / OU Manager