Medtronic

Medtronic Ireland Limited
T Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
www.medtronic.ie

Urgent Field Safety Notice

Defibrillators

Return for Engineering Evaluation

May 2024

Account / Hospital (redacted, letter sent to affected accounts only)

Medtronic Reference: FA1416

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).

Product Name	CFN	GTIN	Serial Numbers
CRTD COBALT HF QUAD MRI IS4 DF4	DTPB2QQ	00763000178192	RTK624606S
CRTD COBALT XT HF QUAD MRI IS4 DF1	DTPA2Q1	00763000711177	RTD607370S
ICD COBALT XT VR MRI IS1 DF1	DVPA2D1	00763000711344	RSC604655S
ICD COBALT XT VR MRI IS1 DF1	DVPA2D1	00763000711344	RSC604647S

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.

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

Keith Taverner: Principal Regulatory Affairs Specialist UK & Ireland