Medtronic

Urgent Field Safety Notice

For Ten (10) Non-Implanted Medtronic Cobalt™ XT Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs)

RETRIEVAL OF NON-IMPLANTED DEVICES

August 2020,

Medtronic Reference: FA925

Dear Healthcare Provider or Supply Chain Distributor,

On August 5, 2020, Medtronic initiated retrieval of ten (10) non-implanted Cobalt™ XT Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs). You are receiving this letter because you were in possession of one or more of these devices identified for retrieval. Below is a list of impacted Serial Numbers.

Device Model	Serial Number
Cobalt XT DR DF4	RSM601547S
Cobalt XT DR DF4	RSM601552S
Cobalt XT DR DF4	RSM601555S
Cobalt XT DR DF4	RSM601556S
Cobalt XT DR DF4	RSM601557S
Cobalt XT HF DF4	RTG600741S
Cobalt XT HF DF4	RTG600742S
Cobalt XT HF DF4	RTG600743S
Cobalt XT HF DF1	RTH600702S
Cobalt XT HF DF1	RTH600707S

Medtronic's internal processes identified these ten (10) devices underwent a specific manufacturing sequence that may have introduced a component issue that could impact device performance including potential loss of function. To mitigate patient safety risk, Medtronic took immediate action to retrieve the ten (10) devices for further engineering evaluation, and to prevent any of these ten (10) sold or consigned devices from being implanted while we complete our investigation. No implanted devices or any other sold or distributed products are in scope of this communication.

This letter serves as a notification for your records regarding the retrieval of these non-implanted product; no further actions are needed.

The Competent Authority of your country has been notified of this action.

If you have any questions or need assistance with product replacement, please contact your local Medtronic Representative at <XXXX>.

Sincerely,

Local / BU Manager