Medtronic Ireland Ltd
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Tel. 353 1 511 1400
Fax 353 1 872 2077
vat IE 9513488W

Urgent Field Safety Notice

Medtronic CryoConsole

Model Numbers: 106A3, 106E2, 106A2-K

2 September 2015

Medtronic Reference: FA677

Dear Customer/Risk Manager:

Medtronic has identified a performance issue with a USB memory component contained within a subset of CryoConsole models listed above. **No injuries have been reported related to this issue.**

Through 21 August 2015, Medtronic has received three (3) reports where the related issue was confirmed out of 106 potentially affected CryoConsole systems installed at customer sites worldwide. Each of these 3 events triggered a system notice that resulted in extended procedure time with no adverse patient events. The issue could potentially prevent completion of the procedure if the user cannot resolve the system notice(s).

Medtronic records indicate that your facility has a CryoConsole system that is potentially affected by this issue. You may continue to use your CryoConsole as per the operator's manual; if a system notice appears, carefully read and follow the instructions in the screen of the console. Your Medtronic AF Solutions representative will contact you to arrange for service of your CryoConsole system.

Please share this notification with others in your organization as appropriate. If a CryoConsole system within scope of this issue has been forwarded to another facility, please notify your Medtronic AF Solutions representative.

Medtronic has notified the Competent Authority of your country of this action.

We appreciate your cooperation and apologize for the inconvenience that this issue may cause. Should you have any questions, please contact your Medtronic AF Solutions representative directly or via Customer Services Tel no 353 1511 1400.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland