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

Urgent Field Safety Notice
DLP® Left Heart Vent Catheters
Recall

Product Name	Model Numbers
DLP® Left Heart Vent Catheters, 16 Fr	**12116**
DLP® Left Heart Vent Catheters, 18 Fr	**12118**

August 2021

Medtronic Reference: FA1186

Dear Risk Manager or Healthcare professional,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific models of unused DLP® Left Heart Vent Catheters, 16 Fr (model 12116) and 18 Fr (model 12118) due to the potential for a wire protrusion through the left heart vent catheter tip. If unnoticed prior to the procedure, this wire protrusion could lead to tissue damage (abrasion/perforation) and thereby to a longer duration of the procedure and/or surgical repair.

Through Aug 09, 2021, Medtronic has received fourteen (14) complaints involving this issue. Three (3) of these reported tissue damage or perforation, requiring surgical repair. No other adverse patient effects have been reported.

In those procedures where a Model 12116 or Model 12118 was used, monitor patients in the acute post-op care setting for bleeding, as this may indicate perforation or abrasion due to wire protrusion. Following acute post-op care setting and discharge, no additional actions for patients are recommended other than normal patient monitoring in accordance with your medical facility's standard care protocol.

Customer Instructions:

Medtronic records indicate that your facility has received one or more of the affected DLP Left Heart Vent Catheters. As a result, Medtronic requests that you immediately take the following actions:

- Identify and quarantine all unused affected DLP Left Heart Vent Catheters as listed in the table above.
- Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return of this product

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Medtronic

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions related to this issue, please contact your local Medtronic representative at 01 511 1400.

Sincerely,

Bethany Moxon
Associate Regulatory Affairs Specialist – UK and Ireland