Medtronic

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URGENT: MEDICAL DEVICE RECALL

DxTerity™ Diagnostic Catheter

Model	Lot Number
U5TRAN35	60068186

17 August 2018

Dear **Risk Manager or Health Care Professional:**
CC:The Chairman Medical Board and relevant Head of Departments

The purpose of this letter is to advise you that Medtronic is voluntarily recalling one (1) lot number of the DxTerity™ Diagnostic Catheter, as indicated above.

Issue Description:

Medtronic has determined that the French size indicator on the inner pouch may incorrectly reflect a 6 French size, rather than the correct 5 French size. The catheters inside the pouch are the correct U5TRAN35 item, the outer carton has all the correct labeling, and all the other information and configuration details on both the carton and the pouch are correct.

If the incorrect size is inadvertently used, the most likely impact is a clinically insignificant delay in the procedure time.

Through 9 August 2018, we have received complaints from one (1) account involving ten (10) mislabeled model U5TRAN35 DxTerity Diagnostic Catheters. **There were no adverse events or harms associated with the complaints.**

There are no actions required for patients already treated with this device. These patients should continue to be monitored in accordance with your standard practice.

There is one additional lot number affected by this issue; model DXT5JL40, lot #60074805. All customers with affected DXT5JL40 have previously been notified.

Actions:

Medtronic's records indicate that your facility has received product potentially affected by this issue. As a result, Medtronic requests that you immediately take the following actions:

1. Identify and quarantine all unused affected product as listed in your inventory.
2. Return all unused affected product in your inventory to Medtronic. Contact your local Medtronic Representative to initiate a product return.
3. Complete the enclosed Customer Confirmation Certificate and return to your local Medtronic Representative even if you do not have any more inventory to return.

Please forward this notice to those within your organization who need to be aware, or to any organization where the potentially affected devices have been transferred.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

f you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

Diana Teo
Quality Management System Manager
South East Asia
Medtronic

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Recall Customer Confirmation Form

Tools Database Package Version 1.288 CD

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
	Name:
Hospital :	**Contact:**
Address:	**Email:**
Phone no:	
E-mail:	

Product Code of the affected System	Serial # of the affected System

I have read and understand the instructions provided and taken and acknowledge receipt of the dated 8 August 2018 by signing below:

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____