Medtronic
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URGENT: MEDICAL DEVICE RECALL

Prevail™ Paclitaxel-coated PTCA Balloon Catheter

Prevail Paclitaxel-coated PTCA Balloon Catheter	
Model Number	**Serial Number/Lot Number**
PRV025020RX	0010853342 0010841909
PRV025030RX	0010837068
PRV035015RX	0010837067 0010765701
PRV035020RX	0010832009
PRV035025RX	0010815239

03 February 2022

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Risk Manager/Health Care Professional:

The purpose of this letter is to inform you that Medtronic is voluntarily recalling a subset of both the 2.5mm and 3.5mm diameter Prevail™ Paclitaxel-coated PTCA Balloon Catheters (herein referred to as Prevail catheters) due to the potential inclusion of an incorrect compliance chart. The affected units are part of the lots listed in the table above. Medtronic records indicate that your facility has purchased one or more of the affected products listed. No other product model or lot numbers are affected by this issue.

Issue Description:
During a Medtronic inspection of 3.5mm Prevail Catheters, a number of these finished products were found to contain an incorrect compliance chart. The compliance chart for the 2.5mm version of the Prevail catheters was included instead of the correct 3.5mm compliance chart for some packaged

3.5mm Prevail catheters. Similarly, some of the 2.5mm Prevail catheter kits may include the 3.5mm compliance chart. Therefore, Medtronic is asking for your assistance to return unused listed product.

This issue was discovered by Medtronic internally, and as of 20 December 2021, there have been no complaints reported for this issue from customers. The potential patient harms of using the incorrect chart include intimal dissection or re-occlusion. There have been no reports of injuries associated with this issue.

For affected product that has been used, no action is necessary, and patients should continue to be managed in accordance with your standard patient management protocol.

Customer Actions:
To mitigate risks associated with this issue, Medtronic is requesting that you carry out the actions below:

- Please review your inventory for listed product.
- Immediately identify and quarantine all unused, listed product in your inventory.
- Please work with your local Medtronic field representative for the return of your product/s.
- Complete the enclosed Customer Confirmation Form and scan and email or hand back to your local Medtronic field representative.

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. Please transfer this notice to other organizations on which this action has an impact.

Please maintain a copy of this notice in your records.

Additional Information:
Medtronic is communicating this information to the appropriate regulatory agency in your country.

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 local Medtronic field representative.

Sincerely,

Diana Teo
Medtronic QRA Lead
Singapore and Malaysia

Chloe Tan
Medtronic QRA Lead
Indochina and Frontier Market Plus

Parichart Bunjobchokchai
Medtronic QRA Lead
Thailand

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Customer Confirmation Form

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For completion by Medtronic Customers Only - Please complete all fields below and return all pages immediately, even if you do not have any product to return.

Even if you have no affected stock to be returned, please tick the appropriate box, and fill out the table below.
Please select only ONE:

☐ No, **no affected inventory** to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

☐ Yes, **affected inventory to be returned**. I have examined our inventory and have the following affected product/s that remain/s unconsumed and is to be returned:

Product Number	Batch Number	Quantity

**If this table is not enough, please use the additional page. Additional page and/or attachments must be signed and dated.*

By signing this form I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated 03 February 2022, from Medtronic regarding Prevail™ Paclitaxel-coated PTCA Balloon Catheter and taken appropriate action.

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

Use this page ***ONLY IF* the space in the previous page is not enough**

Product Number	Batch Number	Quantity

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