Medtronic

Urgent Field Safety Notice

Prevail™ Paclitaxel-coated PTCA Balloon Catheter

Recall

Model Number	Lot Number
PRV025020RX	0010853342, 0010841909
PRV025030RX	0010837068
PRV035015RX	0010837067, 0010765701
PRV035020RX	0010832009
PRV035025RX	0010815239

January 2022

Medtronic reference: FA1223

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.

Medtronic

Customer Actions:

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

- Immediately identify and quarantine all unused, listed product in your inventory.
- Return all unused affected devices to Medtronic. Your local Medtronic Field Representative can assist you as necessary in initiating the return and replacement 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. 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 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 any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,