Medtronic

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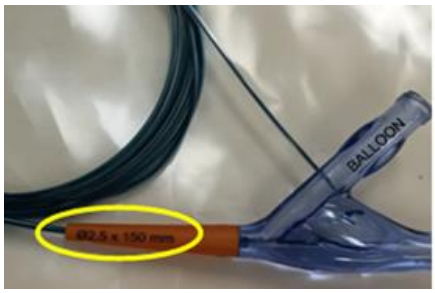
URGENT MEDICAL DEVICE RECALL

PowerCross™ .018" OTW PTA Dilatation Catheter
Model: AB18W030200150
Lot Numbers: A213373, A216702

March 2016

Dear Risk Manager or Health Care Professional:

This letter is to advise you that Medtronic is conducting a voluntary Urgent Medical Device Recall of two lots of the PowerCross™ .018" Over the Wire (OTW) Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter. This recall has been initiated for model AB18W030200150 and is limited to lot numbers A213373 and A216702 affecting 48 units, of which 28 were placed in distribution. These units, with an actual balloon size of 3x200 mm, are incorrectly labeled as 2.5x150 mm on the strain relief (see picture). The correct balloon size labelling of 3x200 mm is included on the outside packaging and pouch of affected devices. According to Medtronic's records, you have received one or more of the potentially affected catheters. This issue does not affect any other Medtronic products or implantable devices.



Strain Relief label

Through 22 March 2016, **Medtronic has received no customer complaints or reports of adverse patient events regarding use of affected catheters**.

Even so, Medtronic is taking precautions in the execution of this recall and has taken steps to prevent distribution of additional affected product. In the unlikely event a physician were to use a 3x200 mm balloon, believing it to be a 2.5x150mm balloon as incorrectly labeled on the strain relief, there is potential to over-expand the diseased vessel potentially resulting in vessel dissection due to the use of a larger diameter of balloon than intended, or over-expand healthy portions of the vessel resulting in vessel spasm due to the use of a greater length of the balloon than intended**. There are no patient actions required. Patients who have received treatment with PowerCross .018" OTW PTA Dilatation Catheter affected by this recall should continue to be monitored in accordance with your standard practice.**

Customer Actions: Please review your inventory for product affected by this issue as listed on the attached Customer Notification Detail Report and perform the following:

- Immediately identify and quarantine all unused, affected product in your inventory.
- Return all unused, affected product in your inventory to Medtronic sales representative. Your Medtronic sales representative can assist you in the return of affected product as necessary.
- Complete the enclosed Customer Confirmation Certificate and return it as directed to confirm your receipt and understanding of this information.

Medtronic has communicated this information to the appropriate regulatory agencies. For questions related to this communication, please contact your Medtronic representative.

Please share this notification with others in your organization as appropriate. If product within the scope of this notification has been forwarded to another facility, please alert the facility of this notification. Medtronic is committed to ensuring its products meet the highest quality standards. We appreciate your cooperation and apologize for any inconvenience this issue may cause.

Sincerely,

[redacted]

Vaidya, Aditya
Aortic & Peripheral Vascular, Business Manager
Medtronic