Medtronic

Urgent Field Safety Notice

MindFrame Capture™ LP

All model and lot numbers

Recall

March 2018

Medtronic reference: FA804

Dear Health Care Professional, Risk Manager,

Medtronic is issuing a recall of the MindFrame Capture™ LP device. All models and all lots of the MindFrame Capture™ LP device are affected by the issue (see Appendix A for the affected model numbers). This is in follow up to the verbal notification Medtronic provided to you end of February related to this issue.

Issue Description:
Medtronic has identified the potential for an issue with all MindFrame Capture™ LP device to partially detach or separate from the delivery wire. Partial detachment or separation of the MindFrame Capture™ LP device may lead to the vessel damage or device foreign body obstructing the blood stream. Potential complications or irreversible injuries associated with this issue include but not limited to: prolonged procedure, incomplete treatment, intimal damage, vasospasm, dissection, intracranial hemorrhage, hematoma, transient ischemic attack, ischemic stroke/cerebral infarction, neurological deficit, and/or death. Through February 23, 2018, Medtronic has received a total of twenty-one (21) reports of partial detachment or separation for the MindFrame Capture™ LP device. **There has been a total of three (3) reports of serious injuries reported which includes two (2) reports of deaths potentially associated with this issue.**

Actions:
In situations where the MindFrame Capture™ LP device stent or stent fragments have been retained, Medtronic is unable to provide specific patient management recommendations at this time due to patient variability associated with these situations. Medtronic is investigating if recommendations can be made to mitigate potential risks associated with this situation and will contact you as soon as possible when these recommendations, if any, become available.

For unexpired affected products that has not been used, Medtronic requests that you take immediate action. Medtronic requests that you immediately take the following actions:

1. Confirm all unused affected product in your inventory is quarantined as requested by previously by Medtronic.
2. Return all affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return of this product as necessary.

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 products have been transferred. Please maintain a copy of this notice in your records.

The Competent Authority of your country has been notified of this action.

We apologise for the impact this may have on you and your patients: please be assured that patient safety and product quality remains our primary concern. Should you have any questions, please contact your Medtronic representative .

Sincerely,

Local /BU Manager

Medtronic

Appendix 1: List of affected Model Numbers

Product Name	Model Number
MindFrame Capture™ LP device	300010 300011 300012 300013 300014 300015 300016 300017 300018