Medtronic

Urgent Field Safety Notice

MindFrame Capture™ LP

Patient Management Recommendations

April 2018

Medtronic reference: FA804

Dear Physician, Health Care Professional,

In February 2018, Medtronic notified customers with unexpired MindFrame Capture™ LP devices of the potential for devices to partially detach or fully separate from the delivery wire. The initial communication requested customers to remove, quarantine and return affected products to Medtronic. This current letter is an additional communication to provide patient management recommendations in the case you experienced a partial detachment or full separation of the MindFrame Capture™ LP device where the device or device fragment(s) were retained in the patient's body.

Our records indicate that you have received a MindFrame Capture™ LP device since commercialization in 2011. In case you are receiving this communication for the first time, Medtronic is detailing the issue, potential complications or irreversible injuries, as well as providing patient management recommendations to manage situations where the device or device fragment(s) were retained in the patient's body.
Affected model numbers are provided in Appendix A.

Issue Description:
Partial detachment or full separation of the MindFrame Capture™ LP device from the delivery wire may lead to vessel damage or a foreign body obstructing the blood stream. Potential complications or irreversible injuries associated with this issue include but are 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. Of the 22 events reported to Medtronic that are associated with partial detachment or full separation of the MindFrame Capture™ LP device as of March 16, 2018, **there have been a total of three (3) reports of serious injury, which include two (2) reports of death that could potentially be associated with this issue.**

Patient Management Recommendations:
Medtronic consulted with an Independent Physician Panel to develop patient management recommendations. If you experienced a partial detachment or full separation of the MindFrame Capture™ LP device during a procedure that resulted in the device or device fragment(s) being retained in the patient's body, Medtronic is providing the following patient management recommendations:

- Consider anti-platelet therapy if clinically indicated, at the provider's clinical discretion.
- Consider close physician follow-up with the patient and repeat imaging if clinically indicated, at the provider's clinical discretion.

Medtronic understands that there is no standard of care for this situation. Given that each patient has unique clinical considerations depending upon patient conditions and individual risk factors, we are unable to provide specific recommendations that would be applicable to all patients

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This notice needs to be passed on to all those who need to be aware within your organization and, as applicable, any associated organizations that may be impacted by this communication. 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,

Appendix A: List of affected Model Numbers

Product Name	Model Number
MindFrame Capture™ LP device	300010 300011 300012 300013