# Medtronic

## Urgent Field Safety Notice

**Pipeline Embolization Device™ (Pipeline Classic), Alligator Retrieval Device™,Xcelerator™ Hydrophilic Guidewire, UltraFlow™ HPCFlow DirectedMicrocatheter, MarathonFlow DirectedMicrocatheter™ Recall**

October2016

Medtronic reference: FA740

Dear Healthcare Professional, Risk Manager,

Medtronic has identified the potential for an issue with a specific set of lot numbers of Medtronic Neurovascular products as noted below where the PTFE (polytetrafluoroethylene) coating could delaminate and separate from the delivery wire. As a result, we are recalling these products. This issue affects all lots of the below Neurovascular products that have an expiration date (Use by Date)**between June 2017 and August 2019** (please refer to Appendix1 for further details):

1. Pipeline Embolization Device™ (Pipeline Classic)
2. Alligator Retrieval Device™
3. Marathon Microcatheter™ Flow Directed (with Stylet)
4. UltraFlow™ HPC Flow Directed Microcather (with Stylet)
5. Xcelerator™ Hydrophilic Guidewire

Note: for the Pipeline Embolization Device™, this issue only affects the delivery wire. The implant itself is not affected.

**Description of the problem:**

Delamination and detachment of the PTFE coating material may lead to PTFE coating in the blood stream. PTFE in the blood stream, depending on its specific size and quantity, could lead to thromboembolic complications or irreversible injuries including but not limited to: intracranial edema, peripheral edema, incomplete treatment, infection, local inflammatory response, systemic inflammatory response, ischemic stroke, lysis/necrosis, neurological deficit, organ impairment, shock, space occupying lesion, thrombosis, and hemorrhage.

Through September 27, 2016, Medtronic has received a total of five (5) reports for the products that are potentially affected by this issue. Medtronic has received no reports of serious injury or patient death as a result of this issue.

**Actions to be taken by the user:**

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.

Our records show that your facility has received one or more of these products as noted above. Consequently, Medtronic requests that you immediately take the following actions:

1. Remove and quarantine all unused affected products in your inventory.
2. Return the potentially affected products to Medtronic. Your Medtronic representative can assist in facilitating the return of product as necessary. If replacement product is needed, your Medtronic representative can assist you with identifying suitable replacement product.

Medtronic has taken the necessary steps to prevent any future shipment of the potentially affected product.

**Transmission of this Field Safety Notice:**

This field safety 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.

# Medtronic

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

We apologise for the inconvenience this may cause you; please be assured that patient safety and product quality remains our primary concern. Should you have any questions, please contact your Medtronic representative at <XXXX>.

Sincerely,

---

Local /BU Manager

Appendix 1 - Identification of affected devices.

Affected devices can be identified based on the Expiration Date (Use by Date YYYY-MM-DD) indicated on the product packaging (see below picture). All lot numbers of the below devices that have a Use by Date**between June 2017 and August 2019** are subject to this recall and need to be returned to Medtronic.

1. Pipeline Embolization Device™ (Pipeline Classic)
2. Alligator Retrieval Device™
3. Marathon Flow Directed Microcatheter™ (with Stylet)
4. UltraFlow™ HPC Flow Directed Microcather (with Stylet)
5. Xcelerator™ Hydrophilic Guidewire