Medtronic News

Medtronic Announces Voluntary Recall of Its Pipeline(TM) Embolization Device, Alligator(TM) Retrieval Device, X-Celerator(TM) Hydrophilic Guidewire, Ultraflow(TM) and Marathon(TM) Flow Directed Micro Catheters

DUBLIN - Oct. 14, 2016 - Medtronic plc (NYSE: MDT) today announced that it has notified customers of a voluntary recall of certain lots of its Pipeline(TM) embolization device, Alligator(TM) retrieval device and X-Celerator(TM) hydrophilic guidewire. The recall also includes the stylet containing UltraFlow(TM) flow directed micro catheters and Marathon(TM) flow directed micro catheters. These products are produced, marketed and sold by Medtronic's Neurovascular business, which is part of the Brain Therapies division in the company's Restorative Therapies Group.

This voluntary recall is being conducted due to the potential separation and detachment of the polytetrafluoroethylene (PTFE) coating on parts of these devices. Should the PTFE separate from the delivery wire or stylets, PTFE particulate could enter the blood stream of the patient. PTFE in the blood stream, based on the size and quantity, could lead to a thromboembolic event.

Medtronic initiated customer communication of the recall by letter on October 5, 2016, and is requesting customers to quarantine all affected product that remain in the inventory and return to Medtronic. The U.S. Food and Drug Administration (FDA) and other regulatory bodies also have been notified.

At the initiation of this recall, 84,278 units potentially affected by this recall had been distributed worldwide. The products were manufactured from July 2014 to September 2016. Additional information about the recall, including the specific lot numbers of affected product, can be found at http://bit.ly/2dTvety.

Medtronic is taking this voluntary action as a precaution and has received no reports of patient injuries to date related to this issue. The full recalled product list of affected lot totals is itemized below:

Product Name	Number of Affected Lots
Pipeline(TM) embolization device	1742
Alligator(TM) retrieval device	171
X-Celerator(TM) hydrophilic guidewires	210
UltraFlow(TM) HPC flow directed micro catheters/ Marathon(TM) flow directed micro catheters	1790

The Pipeline(TM) embolization device is indicated for the endovascular treatment of adults (22 years of age and older) with large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments. The first generation Pipeline(TM) embolization device is affected by this action due to the PTFE coated delivery wire, which is part of the disposable delivery system (the braid implant is not affected). The second-generation device, Pipeline(TM) Flex embolization device, is not affected by this recall.

The Alligator(TM) retrieval device is intended for use in the peripheral and neuro-vasculature for foreign body retrieval. The X-Celerator(TM) hydrophilic guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures. The UltraFlow(TM) flow directed micro catheter is designed for the subselective infusion of physician-specified therapeutic agents such as embolization materials and diagnostic materials such as contrast media in tortuous, distal vessels. The Marathon(TM) Flow Directed Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call +1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to +1-800-FDA-0178.

For information or to report a problem, please contact the Medtronic Lifeline Service at any time at +1-877-526-7890.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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