Medtronic News

Covidien Implements Voluntary Recall of its Pipeline™ Embolization Device and Alligator™ Retrieval Device

DUBLIN, Ireland--(BUSINESS WIRE)--Apr. 11, 2014--Covidien plc today announced that it has notified customers of a voluntary recall to address an issue with certain lots of its Pipeline™ Embolization Device and Alligator™ Retrieval Device where the polytetrafluoroethylene (PTFE) coating applied to the delivery wire could delaminate and detach from the devices.

PTFE coating is used to reduce friction between devices and ease navigation through the vasculature. Delamination of the PTFE coating could potentially lead to embolic occlusion in the cerebral vasculature with the risk of stroke and/or death.

Covidien learned of this issue through internal product testing. The company has not received any reports of patient injuries to date related to this issue.

The Pipeline™ 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 Alligator Retrieval Device is intended for use in the peripheral and neuro-vasculature for foreign body retrieval.

A total of 32 Pipeline Embolization Devices and 621 Alligator Retrieval Devices are affected by this recall. The products were manufactured and distributed from May 2013 to March 2014. This issue involves both the Pipeline Embolization Device sold in the U.S., Australia, France, Germany and United Kingdom, and the Alligator Retrieval Device, which is sold in the U.S., Australia, Canada, Europe and Latin America.

Covidien alerted customers to the recall by letter on April 1, 2014, and is arranging for replacement of the recalled products. The U.S. Food and Drug Administration (FDA) and other regulatory bodies also have been notified.

Adverse reactions or quality problems experienced with the use of this product 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 Covidien Customer Service at 1-800-716-6700 between the hours of 7 a.m. and 7 p.m. (central) or email CustomerServiceUS@Covidien.com.

The recall is expected to have a slight negative effect on sales and earnings in the second half of fiscal 2014. However, the total impact may increase depending on the timing of replacing the recalled products.

ABOUT COVIDIEN

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien develops, manufactures and sells a diverse range of industry-leading medical device and supply products. With 2013 revenue of $10.2 billion, Covidien has more than 38,000 employees worldwide in more than 70 countries, and its products are sold in over 150 countries. Please visit www.covidien.com to learn more about our business.

Source: Covidien plc

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