FDA Classifies Previous Covidien Field Action for Its Trellis-6(TM) and Trellis-8(TM) Peripheral Infusion Systems As a Class 1 Recall

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DUBLIN - February 12, 2015 - Medtronic announced today that a previously communicated global voluntary recall to address an issue with certain lots of its Trellis-6(TM) and Trellis-8(TM) peripheral infusion systems has now been classified as a Class 1 Recall by the U.S. Food and Drug Administration. Customers were previously notified by Covidien of the recall on December 15, 2014. The company has not received any reports of patient injuries related to this issue. If a patient has received treatment with a Trellis 6 or Trellis 8 from the impacted lots, no immediate action is required and physicians should continue to monitor patients in accordance with standard of care.

This action was in response to a manufacturing error where the proximal and distal balloon inflation ports were labeled incorrectly, resulting in the potential for incorrect sequence of balloon deflation. If the physician using the device were to mistakenly deflate the balloons out of order, there is a potential for blood clots to travel downstream and become lodged in the lungs. Depending upon the size and location of these clots, there is the possibility of serious patient injury.

The recall involves 1,248 units manufactured and distributed by Covidien from January 2014 to November 2014. Covidien learned of this issue through customer reports identifying incorrect balloon port identification.

The Trellis-6 and Trellis-8 (Athena) peripheral infusion systems are indicated for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

The recall includes the following models:

Model	Description
BVT608010V01	Trellis 6
BVT608030V01	Trellis 6
BVT612010V01	Trellis 6
BVT612030V01	Trellis 6
CVT808015V01	Trellis 8
CVT808025V01	Trellis 8
CVT812015V01	Trellis 8
CVT812025V01	Trellis 8
EVT808015V01	Trellis 8
EVT808025V01	Trellis 8
EVT812015V01	Trellis 8
EVT812025V01	Trellis 8

Medtronic puts customers and patient safety first, and will continue to work closely with customers and global regulatory authorities to resolve this issue. The company has alerted customers of the recall by letter and is arranging for replacement of the recalled products. The products were distributed in the United States, Europe, Australia, Canada and Turkey. The U.S. Food and Drug Administration (FDA) and other regulatory bodies 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 7:00 a.m. and 7:00 p.m. CT or email CustomerServiceUS@Covidien.com.

ABOUT MEDTRONIC
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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