Medtronic News

Medtronic Announces Voluntary Recall of Diabetes Infusion Sets

DUBLIN - September 11, 2017 - Medtronic plc (NYSE:MDT) announced today that it has started to inform patients worldwide of a voluntary recall of specific lots of infusion sets used with all models of Medtronic insulin pumps. The recall is related to a certain discontinued component in these infusion sets and does not include insulin pumps or glucose sensors.

The company determined, through recent field reports from patients and root cause analysis, that a component, the vent membrane, in the recalled infusion sets may be susceptible to being blocked by fluid during the process of priming/fill-tubing. This situation can lead to potential over-delivery of insulin shortly after an infusion set change, which may cause hypoglycemia. Currently manufactured infusion sets, available to patients since April 2017, include a design update of this component which the company believes reduces the risk of insulin over-delivery after an infusion set change. The company will work with patients to ensure recalled infusion sets with the discontinued component are returned and replaced with new infusion sets containing the updated component at no cost.

Medtronic has contacted the U.S. Food and Drug Administration (FDA), along with other regulatory bodies around the world, to share information related to this issue. Medtronic will continue working directly with government and regulatory authorities on this global voluntary recall.

"Our priority is to work with our patients to mitigate risk to patient safety. While we have shipped a significant number of the new and enhanced sets since April, we are committed to replacing recalled infusion sets for all patients," said Francine Kaufman, M.D., chief medical officer of the Diabetes Group at Medtronic. "Our Medtronic Diabetes team will work as quickly as possible to complete all exchanges to the new and enhanced set and fully support our customers throughout this process."

Customer Instructions

Medtronic recommends that customers use only infusion sets made with the new and enhanced component, the membrane, starting with their next set change. Medtronic would like to remind customers that it is very important to carefully follow the Key Steps document included with the recall notification letter regarding the priming/fill-tubing process - especially if a person only has recalled infusion sets.

Customers in the United States (U.S.) can determine if they have recalled infusion sets by visiting https://checklots.medtronicdiabetes.com.

- See a copy of the U.S. recall notification letter here:www.medtronicdiabetes.com/notice7
- See priming/fill-tubing instructions here: www.medtronicdiabetes.com/priming
- See more information on infusion sets here:www.medtronicdiabetes.com/infusion-sets

Customers outside the U.S. will receive instructions specific to their country. In Europe, Middle East and Africa (EMEA region), customers can determine if they have recalled infusion sets by visiting www.mmc.medtronic-diabetes.com/look.

Patients can always consult the advice of their healthcare professional regarding their medical treatment.

If a customer in the U.S. has experienced an issue with the use of a Medtronic infusion set, please report it to the 24-hour helpline at +1-800-204-7616. Customers can also report adverse events to the FDA's MedWatch Adverse Event Reporting program:

- Online at: http://www.fda.gov/safety/medwatch/howtoreport/default.htm
- Report by telephone: +1-800-FDA-1088
- Fax report: +1-800-FDA-0178

Investor Information

The voluntary recall of infusion sets is not expected to impact Diabetes Group revenue growth in the second quarter or the full fiscal year. The majority of the cost is expected to be incurred in the second quarter, and will depend on a variety of factors, including the amount of unused sets that patients ultimately return, which is difficult to predict. At this point, the cost is not expected to impact earnings per share (EPS) guidance in the second quarter or full fiscal year.

About the Diabetes Group at Medtronic (www.medtronicdiabetes.com)

Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

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 84,000 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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Contacts:

Pamela Reese
Public Relations
+1-818-576-3398

Fernando Vivanco
Public Relations
+1-763-505-3780

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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