Medtronic News

Medtronic Announces Voluntary Worldwide Recall of its StrataMR(TM) Adjustable Valves and Shunts

DUBLIN - April 6, 2017 - Medtronic plc (NYSE: MDT) today announced that on February 22, 2017 it notified customers of a voluntary recall of all unused units of the StrataMR(TM) adjustable valves and shunts. These products are manufactured and marketed by Medtronic's Neurosurgery business, which is part of the Brain Therapies division of the company's Restorative Therapies Group. This recall only applies to StrataMR adjustable valves and shunts and does not apply to Strata(TM) II or Strata(TM) NSC products.

As of the initiation of this recall, 2,622 StrataMR valves and shunts potentially affected by this recall had been distributed worldwide. The affected StrataMR valves and shunts were manufactured from October 27, 2015 to November 11, 2016. Medtronic initiated the recall due to an increase in the product complaint rate. As of April 1, 2017, the product complaint rate related to this issue was 2.75 percent of total units distributed.

Medtronic StrataMR adjustable valves and shunts are used in the management of hydrocephalus. They control the flow of cerebrospinal fluid being drained from the brain to relieve intracranial pressure. Medtronic is conducting this voluntary recall due to an issue that can occur post-implantation that can lead to the potential for under-drainage of cerebrospinal fluid.

Under-drainage of cerebrospinal fluid may result in the following adverse health consequences: headaches, nausea, vomiting and lethargy.

- If any of the affected products have been implanted in patients, physicians should refer to the StrataMR customer recall letter sent February 22, 2017 as well as the valve adjustment instructions in the instructions for use (IFU) for continued patient care.
- Patients and their caregivers should monitor the patient's condition and if they find they are experiencing any of the above-mentioned symptoms, they should consult the physician who implanted the StrataMR valve.

If left untreated, under-drainage can potentially lead to coma and death. There has been one reported patient death, but the cause of death has not been confirmed to be related to this issue.

Medtronic initiated customer communication of the recall by letter and is requesting that customers cease use of all affected product that remains in inventory and return all unused units to Medtronic. 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 online, by regular mail, or by fax.

Multimedia: View sample image of product label (1)

View sample image of product label (2)

Online: Complete and submit the report to 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 further information or to report a problem, please contact Medtronic via phone at +1-800-335-9557 between the hours of 8am and 6pm (EST) or via e-mail at RS.MNSFCA@Medtronic.com.

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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