Medtronic Recalls StrataMR Adjustable Valves and Shunts Which May Cause Fluid Buildup in the Brain

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- Recalled Product: StrataMR Adjustable Valves and Shunts
- Device Model Numbers: Valve, Small - 42955; Valve, Regular - 42965; Shunt Assembly, Small - 46955; Shunt Assembly, Regular - 46965, Snap Shunt Assembly, Small - 46960; Snap Shunt Assembly, Regular - 46970
- Lot Numbers: E03581, E03582, E04352, E04353, E05120, E05121, E06015, E06016, E06138, E06139, E06412, E06476, E09475, E09619, E11655, E11656, E12041, E12265, E12266, E12272, E12273, E12556, E12620, E12752, E12753, E12779, E12780, E12932, E12933, E12934, E12935, E12950, E12951, E12952, E12953, E13482, E13483, E13484, E13485, E13573, E13576, E13641, E13698, E14270, E14518, E14519, E14748, E16247, E18555, E18556, E18557, E18558, E18559, E18560, E19084, E19540, E19670, E19671, E19866, E19867, E22208, E22242
- Manufacturing Dates: October 27, 2015 to November 11, 2016
- Distribution Dates: January 7, 2016 to February 21, 2017
- Devices Recalled in the U.S.: 1,796 units

Device Use

Medtronic StrataMR adjustable valves and shunts are used in the management of **hydrocephalus (https://www.ninds.nih.gov/Disorders/All-Disorders/Hydrocephalus-Information-Page)**. The device provides continuous cerebrospinal fluid flow from the ventricles of the brain into the right atrium of the heart or peritoneal cavity. The design allows the health care provider to non-invasively adjust the valve pressure with a magnetic tool.

Reason for Recall

Medtronic is recalling the StrataMR Adjustable Valves and Shunts due to a design problem which may cause the valve opening pressures to be higher than specified and increase the resistance to the cerebrospinal fluid flow. If this occurs, there is the potential for under-drainage of fluid. Underdrainage occurs when the cerebral spinal fluid is not removed quickly, fluid builds up in the brain cavity and the symptoms of hydrocephalus recur. The use of affected product may cause serious adverse health consequences, including headaches, nausea, vomiting, coma, and death.

Who May be Affected

- Health care providers using StrataMR Adjustable Valves and Shunts
- All patients undergoing procedures involving StrataMR Adjustable Valves and Shunts

What to Do

On, February 22 2017, Medtronic sent an Urgent Medical Device Recall letter to affected customers. The notice also asked customers to:

- Discontinue use of the affected product.
- Account for the number of product units implanted or discarded, and return any unused products by completing individualized customer product accountability form provided in *Attachment A of the letter.*
- Return unused products to Medtronic.
- If any of the indicated products have been implanted in patients, see the **valve adjustments instructions (http://www.medtronic.com/content/dam/medtronic-com-m/mdt/nt/documents/stratamr-adjustment-technical-guide-103015.pdf)** in Attachment B for continued patient care.

Contact Information

Customers with questions related to this recall are instructed to contact Medtronic by phone at 1-800-335-9557 between the hours of 8am and 6pm (EST) or by e-mail at **RS.MNSFCA@Medtronic.com (mailto:RS.MNSFCA@Medtronic.com)**.

Date Recall Initiated

February 22, 2017

Additional Resources

- **Medtronic Press Release (http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2260581)**

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)