Medtronic Ireland Ltd
Block G
Cherrywood Science and Technology Park
Loughlinstown
Co Dublin
Tel. +353 1 5111400

Medtronic

Urgent Field Safety Notice

Medtronic Strata™ II/Strata™ NSC Valves (including Burr Hole and Lumbar Peritoneal [LP])
Valve Magnet Reverse Polarity (Excludes StrataMR™)

Labeling Update

30 January 2017

Medtronic reference: FA753

Medtronic Neurosurgery (Brain Therapies) is initiating a voluntary field safety corrective action for the Medtronic Strata™ II / Strata™ NSC valves (includes Burr Hole and Lumboperitoneal. Excludes StrataMR™). Medtronic is notifying healthcare providers of an Instructions For Use (IFU) Warning update for the affected products by sending a Field Safety Notice.

You are receiving this letter because you may have received one or more of the affected product(s) (see appendix 1). The products identified above may have a rare condition related to the Strata Valve that can lead to an inaccurate pressure level (PL) reading on the Strata™ Indicator Tool or StrataVarius™ system. The condition occurs when the magnet inside the valve becomes reverse polarized*, which may occur only if a patient has been exposed to 3T MRI magnetic field or greater and biological debris is present to an extent that the valve magnet adjustment mechanism is impacted. The IFU for the products will be updated to include the following verbiage to reinforce the warnings/precautions:

> *"Biological debris inside the valve may impact adjustability, and may lead to adjustment mechanism damage if exposed to 3.0 tesla MRI. If difficulty is experienced adjusting or reading the valve setting, radiographic setting confirmation should be considered. The reading from the Strata II Indicator tool or StrataVarius system may be reversed (180 degrees opposite) from the radiographic image. In this situation, radiographic imaging should be used to determine the setting of the valve."*

Our investigation confirms that a reverse-polarity magnet has a relatively small chance of occurrence (Rate: 0.007% over a two year period) and internal testing demonstrates that the condition does not occur during exposure to 1.5 tesla magnetic fields. Over the two year period, a total of five complaints received included three adverse events (three revision surgeries). One revision surgery was confirmed to occur due to the reported product problem. There have been no reports of other instances of disease, illness, or injury. The expected adverse health consequences are the same as those experienced during the course of hydrocephalus management (for example: headaches, lethargy, nausea, vomiting), or those related to a revision surgery.

Immediate Action Required by You:
Read this Field Safety Notice carefully and communicate the issue and recommendations to the other users and concerned parties in your facility.

We recommend you also maintain a copy of this notification for your own records. We request this notice be provided to all those who need to be aware within your organization or to any organization where the potentially affected product may have been transferred.

The Competent Authority of your country has been notified of this action.

We sincerely regret any inconvenience this situation may cause. In case of any questions, please contact your Medtronic Representative at directly or via tel. no: +353 1 5111400.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland

**Reverse polarization of the magnet occurs when the north direction changes to south and the south direction changes to north thereby reversing the polarity of the magnet.*

Appendix 1: List of affected Model Numbers:

23042	42866
27739	44420
27740	44421
27788	44430
27794	44465
27812	46070
27814	46075
27815	46080
27816	46085
27817	46655
27818	46665
27819	46836
27820	46856
27821	46866
27822	46871
27823	46876
27824	46881
27825	46886
27827	92355
27922	92365
42335	92856
42355	92866
42365	96655
42836	96665
42856	