Medtronic

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Urgent – Product Advisory Notice

February 2017

Subject: **Medtronic Strata™ II/Strata™ NSC Valves (including Burr Hole and Lumbar Peritoneal [LP]), All Catalog Numbers, All Lot Numbers, Strata™ Valve Magnet Reverse Polarity (Excludes StrataMR™)**

Dear Chief of Neurosurgery and/or Risk Manager:

Medtronic Neurosurgery (Brain Therapies) is initiating a voluntary field corrective action (FCA) 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 Product Advisory Notice.

You are receiving this letter because you may have received one or more of the affected product(s). 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). However, only one revision surgery was confirmed to occur due to the reported product problem. There have been zero 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.

**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.*

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Immediate Action Required by You:

We are asking you to please take the following steps concerning the communication of this product advisory:

1. Read this Advisory carefully, and communicate the issue and recommendations to the other users and concerned parties in your facility.
2. Complete and return the attached "Customer Acknowledgement Response Form" indicating your receipt, review and further communication (as necessary) of this advisory within your organization.

We recommend you also maintain a copy of this notification and signed copy of the acknowledgement form 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. We sincerely regret any inconvenience this situation may cause.

Sincerely,

[redacted]

Yours Sincerely,
Shirley Loh
Marketing Director

Enclosure: *Customer Acknowledgement Response Form*

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PRODUCT ADVISORY NOTICE

CUSTOMER ACKNOWLEDGMENT RESPONSE FORM

Medtronic Neurosurgery

FCA 2021898-01/06/17-001-C

Medtronic Strata™ II/Strata™ NSC (including Burr Hole & Lumbar Peritoneal) Valves, All Catalog Numbers, All Lot Numbers, Strata™ Valve Magnet Reverse Polarity (Excludes StrataMR™)

I have received, read and notified all appropriate personnel of the information provided in the Medtronic Product Advisory notification regarding Strata™ II / Strata™ NSC [includes Burr Hole & Lumboperitoneal (LP)].

Recipient Name (printed): _____

Recipient Signature: _____ **Date:** _____

Recipient Stamp: _____

Recipient Title: _____

Return this form (keep a copy for your records) to:
POSTAL MAIL:
Medtronic International Ltd., 49 Changi South Avenue 2, Singapore 486056
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+65 6776 6355

Comments/notes: _____