

Medtronic

49 Changi South Avenue 2
Singapore 486056
www.medtronic.com

tel +65 6436 5000
fax +65 6776 6355

URGENT: MEDICAL DEVICE CORRECTION **Medtronic StrataMR Guider Tool Notification**

Model #: 45905, Medtronic StrataMR Adjustment Tool Kit

Affected Lots: 00000, 000004, 000013, 000039, 000041, 000045, 000053, 000054, 000063, 000070, 000076, 000081, 000086, 000092

28 October 2018

Attention: Risk management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Valued Customers:

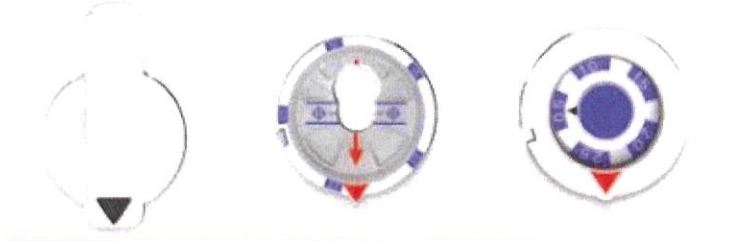

The purpose of this letter is to advise you that Medtronic is initiating a voluntary correction to all lot numbers of the StrataMR Adjustment Tool Kit listed above.

The Medtronic StrataMR Adjustment Tool Set provides a non-invasive method to adjust the pressure/performance setting of StrataMR valves after surgical implantation, to address changing patient needs in the management of hydrocephalus. The StrataMR Adjustment Tool set includes an Adjustment tool, Indicator tool and Locator tool packaged in a nonsterile reusable case. All three tools are required to set or change the pressure/performance level (PL) settings of Medtronic StrataMR valves.

Issue Description:

You are receiving this letter because you may have received one or more of the affected products. Medtronic is initiating a voluntary correction because there is a modification to the StrataMR Adjustment Tool Set which adds a fourth component, the Guider Tool, in order to improve users' ability to reliably adjust StrataMR valves and mitigate the potential of valve rotor foot being positioned on top of an MRI resistance wall, which has the potential of causing a higher than intended flow resistance. There is no change to the design of the existing three tools of the StrataMR adjustment tool sets. The StrataMR valves and shunts have been removed from the market as of February, 2017, therefore this correction is intended for use with patients who currently have the StrataMR valves implanted.

Images of StrataMR Adjustment Tool Set and Guider Tool:

Current StrataMR Adjustment Tool Set Components (Model Number 45095):	New StrataMR Guider Tool (Model Number 45910):
 <div style="display: flex; justify-content: space-around; margin-top: 5px;"> ADJUSTMENT TOOL LOCATOR TOOL INDICATOR TOOL </div>	 <div style="text-align: center; margin-top: 5px;"> GUIDER TOOL </div>

Actions To Be Taken:

1. The current StrataMR Adjustment Tool Set is to be converted to include the new StrataMR Guider Tool. Your Sales Rep will perform the conversion to include the new StrataMR Guider Tool to your existing tool set and provide brief instruction on its use.
2. Please refer to the StrataMR Guider Tool Instructions for Use. It is recommended that the Guider Tool be utilized with the complete StrataMR Adjustment Tool set for all pressure adjustments to existing implanted StrataMR valves.
3. Once the conversion is complete, the Sales Rep will document the conversion was completed on the "Medtronic Representative Confirmation Form" and return it to your local Medtronic Representative.

This letter is intended to document this event for your files. We request this letter be provided to all those who need to be aware of this matter within your organization or to any organization where the potentially affected product may be used.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this Field Corrective Action, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Diana Teo
 Quality Management System Manager
 South East Asia
 Medtronic

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Customer Corrective Action Confirmation Form Medtronic StrataMR Guider Tool Notification

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ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
	Name:
Hospital :	Contact:
Address:	Email:
Phone no:	
E-mail:	

The StrataMR Guider Tool Conversion has been completed for products listed below.

Please fill-in below the quantity on-hand to convert and the 45910 Lot Number used in the conversion.

45905 Lot Number or Serial number	Invoice number	Invoice Date	Qty Shipped (units)	Qty On-hand to convert (units)	45910 Lot Number used in conversion

By signing this form, I confirm that I have read the **Medtronic StrataMR Guider Tool Notification Letter, dated 8 October 2018, from Medtronic** the FCA Notification Letter AND performed the StrataMR Guider Tool Conversion including review of the IFU changes. I will also communicate this information within the organization as required.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____