



Urgent Field Safety Notice

Medtronic StrataMR Guider Tool

Model #: 45905, Medtronic StrataMR Adjustment Tool Kit

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

November 2018

Medtronic reference: FA849

Dear Risk Manager / Healthcare Professional:

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 March 2017 (FA759), therefore this correction is intended for use with patients who currently have the StrataMR valves implanted.

Potential risk of issue of rotor foot on wall:

The StrataMR valve Pressure Level (PL) adjustment procedure requires the rotor foot to travel over MRI resistance walls(s) to reach the intended PL setting. The rotor foot must be seated within a PL setting well to achieve the intended pressure-flow performance. If the rotor foot is incorrectly positioned on top of an MRI resistance wall during pressure level adjustment, this can cause increased valve opening pressures, reducing CSF flow through the valve, thus leading to inadequate CSF draining.

Images of StrataMR Adjustment Tool Set and Guider Tool:

Current StrataMR Adjustment Tool Set Components (Model Number 45905):	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.

This letter is intended to document this event for your files. We ask this letter to 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.

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

We sincerely regret any inconvenience this situation may have caused. If you have any questions or concerns, please contact your Medtronic Representative.

Sincerely,