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## **Urgent Field Safety Notice**

### **Synergy™ Cranial (9733763) and StealthStation™ Cranial (9735585) Biopsy Depth Gauge Cycle View Inaccuracy Software Update**

September 2022

**Medtronic Referenz: FA1204 Phase II**

Dear Healthcare Professional:

The purpose of this letter is to notify you that the software update to address the Biopsy Depth Gauge Cycle View Inaccuracy issue is now available. Your Medtronic representative will be performing this software update on your impacted StealthStation™ S7 and i7 system(s) in the coming months. Your Medtronic representative will remove the warning and instructional placard currently attached to your system when the update is complete.

**Issue Background:** In November 2021 Medtronic issued a notification detailing this issue and provided mitigation steps if the users were to encounter this issue. If the user encounters the software anomaly where the graphical Biopsy Depth Gauge is no longer synchronized with other navigation views, there is the potential to navigate the biopsy needle too shallow or deep to target. This issue can potentially lead to resection of normal brain tissue or eloquent anatomical regions of the brain. When this software

anomaly is encountered, it may result in a prolonged procedure, the need for an additional surgical procedure, tissue injury, including potential for life-threatening injury (hemorrhage, unintended tissue damage, permanent neurological injury), which could lead to death.

Between 01-Jan-2019 and 05-Jul-2022, Medtronic has received four (4) complaints, with two confirmed to be directly related to this software anomaly. The remaining complaints indicate an inaccuracy occurred during a cranial biopsy procedure; however, the provided information is insufficient to confirm whether those were directly related to this software anomaly. There has been one report of patient injury. A copy of the original notification letter has been attached for your convenience and includes the issue description, risks, and previously communicated mitigations.

The mitigations remain applicable until the software has been updated. The Synergy™ Cranial model 9733763 software is being updated to version 2.2.9, and the StealthStation™ Cranial model 9735585 software is being updated to version 3.1.4.

**Required Actions:**

1. Please review this information with all physician users. If you have any questions related to this issue, please contact your Medtronic field representative.
2. Please complete the enclosed Customer Acknowledgement Form and email to <XXXXX>.
3. Please maintain a copy of all records associated with this action.

**Regulatory Notification:**

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Please contact your Medtronic Field Representative if you have any questions regarding this communication.

Sincerely,

Medtronic (Schweiz) AG

**Enclosures:**

- November 2021 Notification