

Urgent Field Safety Notice **StealthStation™ Cranial and Synergy™ Cranial** Depth Gauge Inaccuracy

March 2019

Medtronic reference: FA848 Phase II

Dear Healthcare Professional,

In October 2018, Medtronic notified customers of a software error present in the StealthStation™ S7 and StealthStation™ i7 Synergy™ Cranial Software which could lead to inaccurate placement of a biopsy needle. As a follow up, this letter is intended to provide further information on the issue including additional actions that Medtronic is taking.

Additional Actions and Information

Medtronic has committed to the following two (2) additional actions:

- Update the software to correct this error. Your local Medtronic representative will inform you when this software release is available to install on your system.
- Attach a laminated card to the handle of your StealthStation™ S7 until the updated software is installed to ensure you have the information you need to safely use your system and avoid this potential risk. You may continue to use your device at your clinical discretion, but please be aware of this issue, risks, and the mitigations listed below to eliminate the risks.

Scope and Likelihood of Issue

In order for this software error to occur, ALL of the following must happen:

- The biopsy needle mechanical depth stop on any manufacturers needle is not used,
- The projection is set longer than the plan,
- The projection is navigated when locking the trajectory, AND
- The graphical representation in the Biopsy Depth Gauge feature is only viewed without viewing the navigated views and the overlay of the biopsy needle.

If performed, these actions will cause the Biopsy Depth Gauge graphical display inaccurately depicting the tip of the instrument. The instrument will appear to not have reached the plan target and could cause the biopsy needle to be inserted too deeply, resulting in potential biopsy of healthy tissue or damage to critical structures.

This error is present in StealthStation™ S7 Synergy™ Cranial Software versions 2.2.0, 2.2.5, 2.2.6, and 2.2.7, and in StealthStation™ Cranial Software versions 3.0.0, 3.0.1, 3.0.2 and 3.1.0. The likelihood of occurrence is low, and the confirmed occurrence rate is 0.018% worldwide. Since 2011, Medtronic has received 32 potential complaints (total potential occurrence rate is 0.074%), including eight (8) confirmed complaints related to this software error, one (1) in which healthy tissue was biopsied. 19 additional harms which are likely not related, but could not be excluded based upon available information, involved the sampling of healthy tissue, additional passes of the biopsy needle, additional surgery or a transition to open biopsy. There have been no reported patient deaths.

Mitigations to Eliminate this Risk

- Per the Cranial Software Pocket Guide, always use the Biopsy Needle Mechanical Depth Stop.
- Do not set a projection longer than the length of the surgical plan.
- Ensure Navigate Instrument Tip setting is selected prior to locking the trajectory and subsequently navigating the instrument (see graphic on right).

Regulatory Reporting

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

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

Sincerely,

Local/BU Manager

