Medtronic recalls StealthStation auto-registration feature due to inaccuracies during deep brain stimulation (DBS) procedures

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Medtronic StealthStation Auto-registration Feature from the Cranial software version 3.0 or newer (3.0, 3.1, 3.1.1) with StealthStation DBS License or StealthStation S8 Software with Stealth DBS License
- Distribution Dates: February 1, 2016 to May 1, 2019
- Devices Recalled in the U.S.: 54 consignees were notified with affected product.
- Date Initiated by Firm: August 9, 2019

Device Use

The StealthStation DBS Software with the NexFrame Stereotactic System and O-arm Imaging System provides images of a patient's brain to help surgeons navigate surgical tools and implants used during a deep brain stimulation (https://medlineplus.gov/ency/article/007453.htm) (DBS) procedure.

Reason for Recall

Medtronic has recalled the auto-registration feature of the StealthStation DBS Software due to inaccuracies caused by minor patient movements during the auto-registration process when used with NexFrame during a DBS procedure, which may not be detected by the surgeon or the device system. This may provide inaccurate registration data which could lead surgeons to inaccurately navigate lead placement during image guided DBS procedures. This could result in serious or life-threatening patient harm.

As of June 2020, a total of 33 medical device reports were identified: 22 related to device malfunction and 11 related to injuries.

Who May be Affected

- Healthcare providers using the StealthStation DBS Software in conjunction with the NexFrame Stereotactic System during a DBS procedure.

- All patients who undergo a DBS procedure with the use of the StealthStation DBS Software with the NexFrame Stereotactic System using the auto-registration workflow.

What to Do

On August 9, 2019, Medtronic sent Urgent Medical Device Correction letters to all affected customers. The letter advised physicians to weigh the benefits vs. risks of fiducial-based or fiducial-less registration methods and provided the following instructions:

Following the O-arm auto-registration step, but prior to using the StealthStation DBS Software with the NexFrame Stereotactic System and O-arm Imaging System for intraoperative navigation:

1. Assess navigational accuracy by verifying the accuracy of the registration on several known anatomical landmarks, as described in the indications for use, before using the registration for navigation.
2. Use the StealthMerge functionality in the software, as described in the indications for use, to compare the actual location of the cannula or lead to the surgical plan.
3. Use the planning functionality in the software, as described in the indications for use, to compare the cannula to planned trajectory. This can be accomplished by making an additional plan along the axis of the cannula to evaluate cannula position.

Medtronic has also added instructions to the label on how to use the device and software. In addition, Medtronic has an updated training program to inform physicians of the inaccuracies due to undetected patient motion that resulted in this recall. FDA is continuing to work with Medtronic to determine whether additional mitigations may be needed.

Contact Information

Health care professionals and distributors with questions about this recall should contact Medtronic and call 1-888-826-5603 or email rs.navtechsupport@medtronic.com. (mailto:rs.navtechsupport@medtronic.com)

Additional Resources:

- Medical Device Recall Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=180357)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event

Reporting Program using an online form, regular mail, or FAX.