Brainlab AG Recalls Spine & Trauma 3D Navigation Due to Inaccurate Display That May Result in User Misinterpretation

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:

- Brainlab Spine & Trauma 3D Navigation 1.0
- Product code: HAW
- Manufacturing Dates: May 2018 to February 2019
- Distribution Dates: May 2018 to February 2019
- Devices Recalled in the U.S.: 60

Device Use

The **Brainlab Spine & Trauma 3D Navigation Software (https://www.brainlab.com/surgery-products/overview-spinal-trauma-products/)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**, used with the Brainlab Spine & Trauma Navigation System, provides patient images to help surgeons safely navigate surgical tools and implants used before and during minimally invasive surgical procedures.

Reason for Recall

Brainlab is recalling the Spine & Trauma 3D Navigation Software due to the potential for incorrect information to display during surgery that may prevent the surgeon from accurately navigating surgical tools inside the patient. This may result in:

- Damage to the patient's body,
- A second, otherwise unnecessary, surgical procedure, or
- Serious life-threatening patient injuries or death.

Who May be Affected

- Health care providers using the Brainlab Spine & Trauma 3D Navigation Software.

- All patients who undergo a procedure with the use of the Brainlab Spine & Trauma 3D Navigation Software may have this issue occur during their surgery.

What to Do

Brainlab notified consignees of the problem on March 1, 2019, and directed consignees to:

1. Avoid workflow changes with already registered datasets, if possible. For intraoperative screw planning, avoid switching between the workflow application selections "3D Navigation Intraoperative Imaging" and "3D Navigation" during one patient treatment.
2. After restarting the application with a previously registered dataset (crash restore or workflow change), always activate and deactivate the sub-menu "Orientation" once to ensure that the correct, expected view representations are displayed for the current session.
3. Continue to follow instructions and warnings in the user guide, particularly regarding maintaining navigation accuracy and avoiding reference displacement.

Brainlab plans to stop distributing this software as soon as an updated version is released and available for distribution.

For more information, please reference the **Navigational Accuracy Errors Associated with Frameless Stereotaxic (Stereotactic) Navigation Systems: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm563249.htm)**, which includes recommendations for health care providers.

Contact Information

Health care professionals and distributors in the U.S. with questions should call 1-800-597-5911 or email **us.support@brainlab.com (mailto:us.support@brainlab.com)**.

Date Recall Initiated:

March 1, 2019

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2019 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm629347.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)