Navigational Accuracy Errors Associated with Frameless Stereotaxic Navigation Systems: FDA Safety Communication

Date Issued: June 15, 2017

Audiences:

- Health care providers who use frameless stereotaxic navigation devices including Ear, Nose and Throat Specialists, Neurological Surgeons, Orthopedic Surgeons and Oral/Maxillofacial Surgeons

Medical Specialties: Otolaryngology, Neurosurgery, Orthopedics, Oral Surgery

Device: Stereotaxic navigation systems include a computer system that utilizes patient imaging (e.g., CT, MRI) to guide surgeons with the placement of specialized surgical instruments and implants before and during the procedure. Stereotaxic systems are generally considered framed or frameless.

- Frame-based stereotaxic navigation systems require the attachment of a frame to the patient's head using screws or pins. These systems rely upon the fixed location of the frame to calculate a trajectory and distance to a point of interest identified on the patient's image.
- Frameless stereotaxic navigation systems generally do not require the placement of a frame on the patient's anatomy and tend to be more commonly used. These systems rely upon various technologies to track the location of the patient and navigated instruments in 3D space relative to registered patient imagery.

The stereotaxic navigation system identifies and registers certain anatomical landmarks between the tracked patient's rigid anatomy and the patient's radiographic images. During surgery, the surgeon uses specialized instruments (e.g., drivers, cut guides, needles) navigated by optical, electromagnetic, or other tracking methods to provide continuous, real-time visualization of the instruments' position overlaid on the patient's images. The system creates 2-D and 3-D images, which guide and assist the surgeon before and during the procedure.

Depending on the system and the accessories, a stereotaxic navigation system may be used during surgical procedures such as diagnostic biopsies, tumor resections, bone preparation and implant placement, placement of electrodes, otolaryngologic, or neurosurgical procedures.

While this communication is focused on frameless stereotaxic navigation systems since these systems are more commonly used, many of the recommendations provided are applicable to framed and frameless stereotaxic navigation systems.

Purpose:
The FDA is issuing this communication to make health care providers aware of possible navigational accuracy errors that may occur when using frameless stereotaxic navigation systems. Be aware that based on current information, the FDA believes the overall benefits of using frameless stereotaxic navigation systems continue to outweigh the risks and the Agency has not determined that any particular system carries greater risk than others.

This communication also contains recommendations for surgeons to consider to help mitigate associated risks to patients, including repeatedly assessing the navigational accuracy throughout a procedure when using a frameless surgical navigation system.

Summary of Problem and Scope:
The FDA is aware that some health care providers have experienced navigational accuracy errors during surgical procedures when using frameless stereotaxic navigation systems. Some of these errors have led to patient deaths, serious or life-threatening injuries, and inaccurate, aborted, or prolonged medical procedures.

Based on our analysis, the FDA believes that there are many factors that contribute to these errors, and no particular system carries greater risk than others.

FDA analyzed data from multiple sources and determined that navigational accuracy errors may occur due to problems associated with one or more of the following:

- *Navigation Software and Hardware*, including software anomalies and hardware damage or defects;
- *System Complexity (Human Factors),* including use errors in inputs, system setup and execution of system and surgical techniques;
- *Compatibility*, including the use of incompatible accessory instruments with the stereotaxic navigation system;
- *Anatomical Complexity*, including surgical requirements and intraoperative shift (e.g., brain shift, local tissue deformation from tissue resection, spinal movement);
- *Registration & Tracking,* including poor registration and movement of the registration fiducials or reference array; and
- *Medical Image Quality*, including insufficient image resolution and incomplete images.

Recommendations for Health Care Providers:
The FDA recommends that health care providers consider the following information and actions to reduce the potential of serious adverse events:

- Be aware that based on current information, the FDA believes the overall benefits of these devices continue to outweigh the risks in appropriately selected patients when used by properly trained surgeons, and we have not determined that any particular system carries greater risk than others.
- Assess navigational accuracy repeatedly throughout a procedure when using a surgical navigation system.
  - Reconfirm accuracy by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.
  - If the stereotaxic navigation system does not appear to be accurate despite troubleshooting (e.g., resetting the system), do not rely on the navigation system.

Navigation Software and Hardware

- Be aware of any manufacturer's recommended software updates related to the safe performance of the system, and update as needed.
- Inspect the stereotaxic navigational system, including any components or accessory devices, prior to each use.
- Do not use devices, components, or accessories if they are visibly damaged, have been dropped or are not performing as expected.
  - Remove any defective component or accessory from inventory and return it to the manufacturer for maintenance and inspection.
- Be aware of the stereotaxic navigation system's technological principles and limitations including:
  - Electromagnetic based navigation systems are subject to interference from metallic objects or other emitters that can impact navigational accuracy, or may interfere with other devices and/or implants. If you suspect interference, move equipment further apart, use a radio frequency barrier, or do not use the stereotaxic navigation system if it is not operating as intended.
  - Optical-based navigation systems may experience line-of-sight issues that may require hardware re-positioning or interference from infrared light sources. If you suspect interference, move equipment further apart, discontinue use of the infrared emitter, or do not use the stereotaxic navigation system if it is not operating as intended.

System Complexity

- Be aware of the operating principles and limitations.
  - Select the appropriate accessories for the surgical procedure. Be aware that not all accessories are appropriate for all applications (e.g. minimally invasive procedure accessories versus open procedure accessories).
  - Understand error modes and recovery methods.
  - Understand the stereotaxic navigation system's accuracy limitations for the specific surgical procedure.
- Review and follow the manufacturer's instructions for use and recommended training, and contact the applicable manufacturer with any questions.

Compatibility

- Be aware that not all surgical instruments are appropriate for stereotaxic navigation.
  - Review the manufacturer's labeling to make sure the instruments are compatible with the stereotaxic navigation system.
- Be aware that some stereotaxic navigation systems are designed to be used with specific instruments that have been modified to support navigation, while others may be compatible with unmodified instruments that are straight and rigid.
  - For example, asymmetrical or flexible instruments may not be appropriate for navigation as the system may not be able to predict the instrument's location.
  - Refer to the manufacturer's instructions for use, or contact the applicable device manufacturer for further information.

Anatomical Complexity

- Be aware that certain stereotaxic navigation applications rely upon a rigid anatomical structure to track the target location.
  - Accuracy decreases when navigating to targets away from the tracked structure due to anatomic shifting experienced during the procedure (e.g., brain shift, local tissue deformation from tissue resection, spinal movement).
  - Position the patient tracker on a rigid anatomical structure as close as possible to the desired navigational target.
  - If navigational accuracy error is suspected, confirm the instrument's position using intra-operative imaging or convert to a non-navigated surgical method.

Registration & Tracking

- Be aware that the registration process establishes baseline navigational accuracy. If prompted by the system, only proceed if the registration error estimate matches your clinical requirements.
- Be aware that several patient tracking methods may be available, but they may not provide the same benefits, risks, and fixation quality.
  - For example, a bone screw-based registration method and a strap-based registration method could be options.
  - Because the navigation system cannot immediately detect movement of the patient reference relative to the tracked anatomy, carefully select a patient tracking method based upon the clinical tolerance for navigational error.

Medical Image Quality

- Select a pre-procedural imaging modality (e.g., CT, MRI, X-ray) that contains the information necessary to accurately complete the planned surgical intervention.
- Ensure that individual patient images are of sufficient quality (e.g., slice thickness, field of view (FOV), spatial resolution, noise level, artifact) and real-time (e.g. represents the patient's anatomical structures) to enable accurate stereotaxic navigation.
- Follow any image acquisition and reconstruction protocols provided by the stereotaxic navigation system manufacturer.
- Consult with a radiologist as needed.

FDA Activities:
The FDA is working with device manufacturers to ensure accurate labeling that includes clear user instructions on how to minimize the occurrence of these issues.

The FDA will keep the public informed as significant new information becomes available.

Reporting Problems to the FDA:
Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**.

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the use of medical devices. Health care providers should submit voluntary reports of device problems associated with accuracy and precision to the Agency via the **Medical Device Reporting (MDR) (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** process. If a health care provider suspects there was a problem with device accuracy or precision, we encourage the health care provider to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**. User facilities participating in the FDA's Medical Product Safety Network (MedSun) should report all of their device-related adverse events through the MedSun reporting site, not through MedWatch.

- When submitting a report to FDA, if possible, please include information related to the brand and model of all instruments used during the procedure, and what instruments were being used at the time the patient injury occurred or was suspected to have occurred. Please also provide any information on how navigation accuracy was assessed before and during the use of the instruments.

Additional Resources:
The Use of Non-Medtronic Devices with Medtronic's NavLock Tracker – Letter to Health Care Providers (/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm556052.htm)

Contact Information:
If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)

2016 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553855.htm)