

April 28, 2017

Re: Safety Notice Related to the Use of Non-Medtronic Instruments with the NavLock™ Tracker

Dear HCP,

Medtronic manufactures a variety of products, including the StealthStation™ Surgical Navigation System. The StealthStation™ offers a spinal navigation solution to aid surgeons in procedures such as spinal fusion. The system includes a navigation system (StealthStation™) and navigated instruments. Medtronic offers a variety of navigated instruments for surgeons to use with the StealthStation™, depending on what task they are trying to accomplish. The most common device used to track instruments is called a NavLock™ Tracker (see Figure 1). NavLock™ is available in four (4) different geometries, and all follow the same design principles.

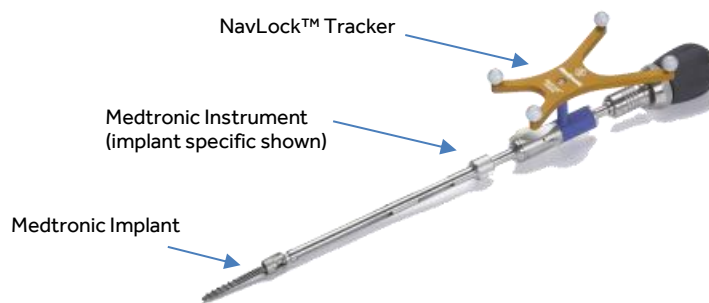


Figure 1.

The NavLock™ Trackers are accessories to the StealthStation System and are designed, rigorously tested and intended to be used only with Medtronic instruments (see Figure 1). Compatible instruments include both general use and implant specific instruments. The general use instruments include awls and probes manufactured by Medtronic. Taps and screwdrivers are examples of instruments manufactured by Medtronic that are intended for use with specific implant systems. Whether for general use or for a specific implant type, instruments manufactured by Medtronic are the only instruments designed, intended for use, and validated by Medtronic to be compatible with the NavLock™ Trackers.

Medtronic has not assisted in the design, instrument development, software development, process qualification, or validation of any non-Medtronic instrument for use with the NavLock™ Tracker. Instruments manufactured by a non-Medtronic manufacturer have not been evaluated by Medtronic for compatibility with NavLock™. Additionally, non-Medtronic instruments do not have corresponding "tool cards" in the StealthStation software.

Medtronic has become aware of occurrences of injuries, minor and serious, including two patient deaths, following procedures in which non-Medtronic instruments were used with the NavLock™ Tracker.

As a result of these events, Medtronic is revising the Indications for Use statement and strengthening the warning statement in the NavLock™ instructions. Medtronic has notified FDA of these changes.

The revised Indications for Use statement is provided below, along with the current statement for comparison:

Revised Indications for Use: The NavLock Trackers are intended to enable navigation of Medtronic instrumentation used during spinal fusion and interbody procedures with the Medtronic StealthStation surgical navigation system. The NavLock™ Trackers should only be used with Medtronic instruments.

Current NavLock Labeling Statement: The NavLock™ Tracker is intended to enable navigation of instrumentation used for pedicle preparation during spinal fusion and interbody procedures with a Medtronic computer assisted surgery system.

The strengthened warning statement is provided below, along with the current warning statement for comparison.

Strengthened Warning: The NavLock™ Tracker is designed and tested for use only with Medtronic instruments. The use of non-Medtronic instruments with the NavLock™ Tracker may result in inaccuracy, leading to serious injury or death.

Existing Warning: The NavLock™ Tracker is designed and tested for use only with Medtronic instruments. Use with any unapproved instrument could compromise accuracy and safety.

Recommend Action:

Only use Medtronic instruments with the NavLock™ Tracker.

This safety notice is specific to the NavLock™ Tracker. If you have questions regarding other Medtronic trackers or instruments used with the StealthStation, please contact us at the number below. Please have the user(s) of these devices complete the attached confirmation form and return the form to us at RS.NavFCA@medtronic.com or fax it to Medtronic Technical Services at 651-367-7075. Retain a copy of this letter in your records for future reference.

Sincerely,



Tom Reimann
Senior Director of Quality Assurance
Medtronic Neurosurgery

Contact Information:

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