Medtronic

Urgent Field Safety Notice

Stealth Autoguide™ Tracker (Model 28248) Potential for Weld Failure

Recall

November 2021

Medtronic Reference: FA1205

Dear Healthcare Professional,

The purpose of this letter is to inform you that Medtronic is conducting a voluntary recall of Stealth Autoguide™ Tracker (28248) which is an instrument in the Stealth Autoguide™ Basic Instrument Kit (9736188) and the Bundle Autoguide™ Reg Kit.

The scope of this action includes all Stealth Autoguide™ Trackers (model number 28248).

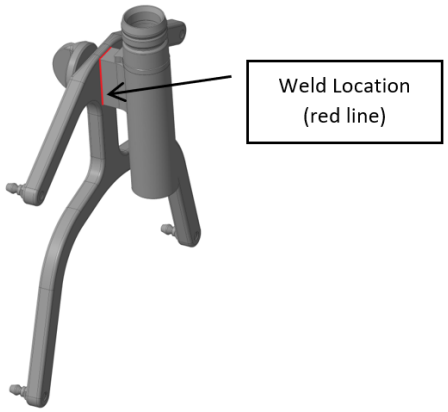
PRODUCT DETAILS

Product Name	Model#/CFN	GTIN
Stealth Autoguide™ Tracker	28248	00763000205874

Issue:

The Stealth Autoguide™ Tracker interfaces with the StealthStation™ Navigation System. The Tracker holds and guides surgical instruments, and the Clinician can secure instruments in the tracker with a knob screw. The StealthStation™ system's infrared camera tracks the position and orientation of the Stealth Autoguide™ Tracker by detecting the spatial location of the passive optical spheres mounted to the tracker.

Medtronic has identified, through internal testing, that the weld where the Tracker connects to the instrument tube may be subject to separation failure. The location of the potential separation failure is depicted in the figure below.



Stealth Autoguide™ Tracker Location of Potential Weld Separation

Potential Health Hazard:
While separation of the Stealth Autoguide™ Tracker at the welded joint has not been reported by customers, Medtronic's testing identified the potential for this to occur and render the device unusable. If the weld separation is not identified prior to use, the issue has the potential to cause navigational inaccuracy. If a weld separation occurs and a navigation inaccuracy is experienced, it may result in prolonged procedure and tissue injury, including the potential for a life-threatening injury (hemorrhage, unintended tissue damage, permanent neurological injury) which could lead to death.

As of October 27, 2021, Medtronic has not identified any customer reported complaints or patient injuries attributed to this issue.

Required Actions:
1) Identify, segregate, and quarantine affected products within your inventory.
2) Contact your Medtronic representative for assistance to return affected product and to schedule replacement.

Information for Alternatives and Replacement Product:
Medtronic is working with its suppliers to make Stealth Autoguide™ Tracker inventory available as soon as possible at which point a replacement device will be provided at no additional cost.

Until replacement product is available, navigated alternatives can be used as options for procedures indicated for Stealth Autoguide™. This includes any neurological condition in which the use of stereotactic surgery may be appropriate (for example, stereotactic biopsy, stereotactic EEG, laser tissue ablation, etc.). Please consult with your Medtronic Sales Representative for options.

ALTERNATIVE PRODUCT USAGE

Procedure Type	Alternate Product for Procedure
Stereotactic Biopsy	Vertek® or Navigus™ Biopsy Solutions
Stereotactic EEG	Vertek® Biopsy Solution
Laser Tissue Ablation	Vertek® Biopsy Solution

Transmission of this Field Safety Notice:
1) This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
2) Please maintain a copy of this notice in your records.

Additional Information:
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 at <**XXXXX**>.

Sincerely,

Local / BU manager