Medtronic
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URGENT: MEDICAL DEVICE CORRECTION

Difficulty in Opening and Removing Spinous Process Clamps

July 14, 2017

Dear Healthcare Professional:

This letter is to notify you of a potential issue which may result in difficulty opening and removing Medtronic Spinous Process Clamps (referred to as Spine Clamps) from patient anatomy and to provide instructions to avoid this issue.

Product Information	
Brand Name:	Spine Referencing Instrumentation
Model Number(s)/ Catalog Number(s):	9734715 Spinous Process Clamp, Tall, GTIN 00643169529403 9734716 Spinous Process Clamp, Short, GTIN 00643169529410 9734723 Double Spinous Process Clamp, Tall GTIN 00643169529427 9734724 Double Spinous Process Clamp, Short GTIN 00643169529434 9735500 Set (contains 9734715 and 9734716), GTIN 00643169540590
Product Description & Usage:	Intended Use When used with a Medtronic StealthStation Navigation System, the Spine Referencing fixation devices are intended to provide rigid attachment between patient and patient reference frame for the duration of the surgery. The devices are intended to be reusable. Description Spine referencing fixation devices provide bony fixation for patient reference frames through the use of: two spinous process clamps; a single spinous process clamp and double spinous process clamp, a screw based reference which will connect between two screw heads, a rod clamp which will attach to existing rods in place, and a percutaneous reference pin. The T-handle driver is used with the spinous process clamps and rod clamps. Both spinous process clamps are available in tall and short post versions for a total of four spinous process clamps.

Issue Description:

Medtronic has become aware of instances where Spine Clamps have been damaged when forced open beyond their intended limits during use and will subsequently not open once attached to a patient's spinous process. When the Spine Clamp is forced open beyond its intended limits, a component (captive washer) may break off. The washer could then be inadvertently left behind in a patient's body if the breakage occurs during the procedure. If the washer is missing from the device, the spine clamp cannot be re-opened after placement on the spinous process. Medtronic has received 6 reports where unintended removal of spinous process occurred when attempting to detach the Spine Clamp. The unintended removal of spinous process can lead to damage of adjacent vertebra and cause premature degradation.

This Medical Device Correction is intended to provide instructions to help healthcare practitioners identify whether a Spine Clamp has been damaged prior to use.

The steps below will allow the determination of whether the washer is present such that the device will operate as designed.

Perform the following steps prior to using the spine clamp in <u>each procedure</u> to ensure that the device is not damaged.

1. Hold the spine clamp by the post with the jaws pointing down. See Figure 1.

2. Use the T-handle to turn the clamp screw.

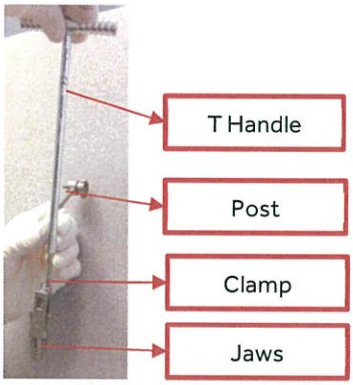

Figure 1

3. By turning T-handle clockwise, **close** the jaws fully to baseline the position of the jaws. See Figure 2a and 2b.

4. Then open the jaws of the clamp by turning The T-handle counter-clockwise. See Figure 2a and 2b.

Figure 2a Single Spine Clamp

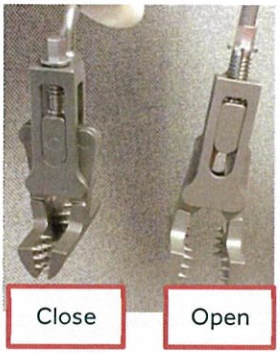

Figure 2b Double Spine Clamp

If the jaws open, the clamp is functioning properly and can be used in the procedure.

Note: Do not continue to turn T-handle if resistance is met as this may cause the captive washer to break off the device.

DO NOT USE THE CLAMP if either of the following occur:

- The jaws remain closed when attempting to open the clamp.
- The clamp screw backs out of the clamp. See Figure 3

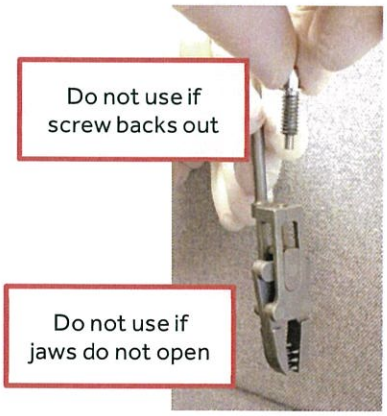

Figure 3 damaged spine clamp

Please follow the instructions above for all spine clamps at your facility immediately upon receipt of this letter. Medtronic has implemented a design mitigation in new Spine Clamps to prevent the user from inadvertently damaging the device by opening beyond its intended limits. The revised spine clamps are available. If you identify a damaged spine clamp due to this issue, please quarantine the device and contact Medtronic Technical Services at 1-800-595-9709.

Actions:
To ensure this information has been received, please complete the attached Consignee Response Form and return the form to us at RS.NavFCA@medtronic.com or fax it to Medtronic Technical Services at 651-367-7075.

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 action, please contact Medtronic Technical Services at 1-800-595-9709.

Sincerely,

[redacted]

Tom Reimann
Senior Director of Quality
Neurosurgery

CC: Chairman of Medical Board and relevant HoDs

Medtronic
49 Changi South Ave 2, Singapore 486056 www.medtronic.com

Medical Device Correction Spine Clamp Consignee Response Form

We acknowledge the receipt of the Medical Device Correction information and will alert the appropriate personnel using these devices.

Facility Name: _____

Facility Address: _____

City, State, and Zip Code: _____

Contact Name and Title (please print): _____

Phone Number: _____

Contact Signature_____ Date: _____

Facility Stamp_____

Return Instructions

Complete and return this form to rs.navfca@medtronic.com or fax to (651) 367-7075.

If you have questions or need replacement product, contact Technical Services at 1-800-595-9709.