

## Urgent Field Safety Notice

### Spinous Process Clamp Tall and Short (Model 9734715 and 9734716) Double Spinous Process Clamp Tall and Short (Model 9734723 and 9734724) Important Device Information

11 July 2017

Medtronic reference: FA774

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.

#### Description of the Issue:

Medtronic has become aware of instances where Spine Clamps have been damaged when forced open beyond its 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 Urgent Field Safety Notice 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 each procedure 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.

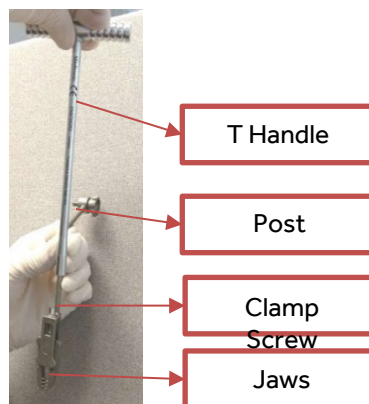


Figure 1

3. By turning T-handle clockwise, **close** the jaws fully to baseline position of the jaws.
4. Then open the jaws of the clamp by turning The T-handle counter-clockwise. See Figure 2a and 2b.

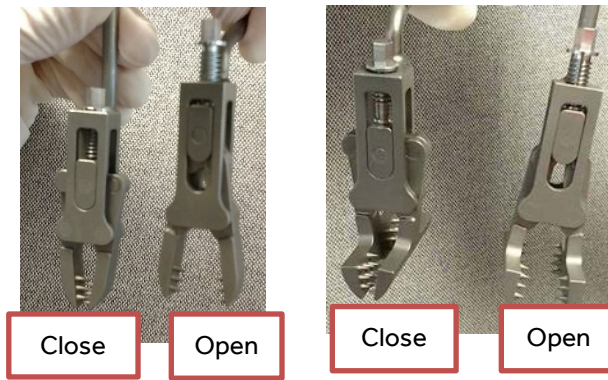


Figure 2a: Single Spine Clamp

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 occurs:**

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

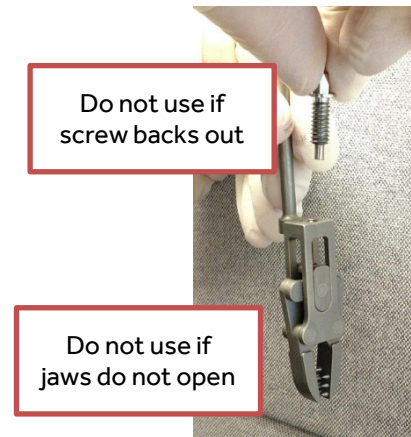


Figure 3: damaged spine clamp

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 your Medtronic Representative.

The Competent Authority of your country has been notified of this action.

We are committed to patient safety and appreciate your prompt attention to this matter. In case of any questions, please contact your Medtronic Representative at <XXXX>.

Sincerely,

Local /BU Manager