Medtronic

Urgent Field Safety Notice

Visualase™ Cooled Laser Applicator System (VCLAS) Tubing Sets

Recall

Model Numbers
VCLAS 9735559 3mm TIP/1.65mm CATHETER
VCLAS 9735560 10mm TIP/1.65mm CATHETER
VCLAS 9735561 15mm TIP/1.85mm CATHETER

July 2019

Medtronic reference: FA877

Dear Healthcare Professional,

This letter is to inform you that Medtronic is recalling Visualase™ Cooled Laser Applicator System (VCLAS) kits due to manufacturing issues impacting the saline tubing sets included in these kits. All kits with lot numbers 0211041602 through 0217695790 are potentially affected by this issue.

Issue Description:
As of June 21, 2019, Medtronic has received 21 complaints on the saline tubing set of all three types of VCLAS kits (3mm, 10mm, 15mm tips). Complaints include incorrect Luer connector assembly, incorrect drip-chamber assembly, and/or excessive adhesive causing tubing occlusion. Per the Instructions for Use (IFU) and Software Confirmation Messages, the user must verify appropriate saline flow and return prior to delivery of laser energy. The reported tubing issues could result in disruption or prevention of saline flow.

Other than short-term delays of procedure, Medtronic has not received any reports of patient injury related to this issue. In cases where affected tubing sets were unable to be used, secondary tubing sets were used. Based on current reports, no Visualase procedures have been cancelled or aborted because of this issue.

Medtronic has identified and corrected the manufacturing issues, and new tubing sets are now available.

Required Actions:

1. Please examine your inventory, and if any of the product with lot numbers from 0211041602 through 0217695790 are found, immediately quarantine it for return to Medtronic.
2. Return all unused affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.

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.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

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 or concerns, please do not hesitate to contact your Medtronic representative at <XXXXX>.

Sincerely,