Medtronic

Urgent Field Safety Notice

Covidien EEA™ Circular Stapler with Tri-Staple™ Technology.

Recall

August, 2018

Medtronic reference: FA838

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific production lots of its Covidien EEA™ Circular Stapler with Tri-Staple™ Technology.

Issue Description:

This recall is being conducted due to the potential for a device to have an incorrect tissue gap. Use of a device with an incorrect tissue gap may result in incomplete staple formation and/or the inability to remove the device from tissue following application potentially leading to bleeding, anastomotic leak or tissue trauma. This issue was identified during in-process Quality testing at the manufacturing facility. There have been no reports of serious injury related to this issue.

This recall affects only the item codes, and lots listed below.

Item Code	Description	Affected Lot Numbers				
TRIEEA28MT	Covidien EEA™ Circular Stapler with Tri-Staple™ Technology 28mm Medium/Thick	P8A0976X	P8B1540X	P8D1405X	P8D1409X	P8E1214X
		P8A0977X	P8C0032X	P8D1406X	P8E1211X	P8E1215X
		P8A0978X	P8C1177X	P8D1407X	P8E1212X	P8E1216X
		P8B1538X	P8C1183X	P8D1408X	P8E1213X	P8E1217X
		P8B1539X				
TRIEEA28XT	Covidien EEA™ Black Circular Stapler with Tri-Staple™ Technology 28mm Extra Thick	P8A0979X	P8C1178X			
TRIEEA31MT	Covidien EEA™ Circular Stapler with Tri-Staple™ Technology 31mm Medium/Thick	P8A0980X	P8B1542X	P8C1179X	P8D1410X	P8E1304X
		P8B1541X	P8C0033X	P8C1180X	P8D1411X	P8E1305X
TRIEEA31XT	Covidien EEA™ Black Circular Stapler with Tri-Staple™ Technology 31mm Extra Thick	P8A0981X	P8C1181X			

Medtronic requests that you quarantine and return any unused products of the item codes and lots detailed above. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed EEA™ Circular staplers with Tri-Staple™ technology listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

Required Actions:

1. Please quarantine and discontinue use of the affected item code and lots listed on page one.
2. Please return affected product as indicated in Appendix A.
3. Complete the Return Verification Form **even if you do not have inventory.**

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

We request that you contact Medtronic if you experienced quality problems or adverse events.

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.

Sincerely,

Local BU signature

Appendix A: Return Instructions:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from **Medtronic**	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a **distributor**	Complete **all** fields on the form and contact your distributor directly to arrange for return of product	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor & to the Medtronic contact provided on the verification form.

Appendix B