Medtronic

Urgent Field Safety Notice

EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology.

April 2018

Medtronic reference: FA811

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™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology.

Issue Description:

This recall is being conducted due to the potential for improper welding of the yellow staple guide to the instrument. Use of a device with an improperly welded staple guide may result in improper staple formation potentially leading to bleeding or anastomotic leak. 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	Item Description	Affected Lots				
HEM3335	EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology 3.5MM	N7J1145MX	N7L0380MX	N7L0762MX	N7L1077MX	N7M0733MX
		N7K0092MX	N7L0457MX	N7L0868MX	N7M0144MX	N7M0835MX
		N7K0692MX	N7L0594MX	N7L0940MX	N7M0185MX	N8A0144MX
		N7K0693MX	N7L0676MX	N7L1076MX	N7M0732MX	N8A0166MX
HEM3348	EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology 4.8MM	N7K0694MX				
		N7L1078MX				
		N7M0837MX				

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 Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ 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 at 00966114048888.

Sincerely,

Medtronic Saudi Arabia LLC

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