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**URGENT: MEDICAL DEVICE RECALL**  
**Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology**

10 April 2018

Dear Valued Customer:

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

CC: The Chairman Medical Board and relevant Head of Departments

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of its

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

**Issue Description:**

This voluntary 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 voluntary 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 codes and lots listed.
2. Please complete the attached Customer Confirmation Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick "No affected inventory to be returned" and revert back to your local Medtronic Representative.
3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

Please complete the Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology Customer Confirmation Form (attached) and return to your local Medtronic representative together with affected units if any.

- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

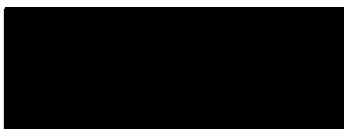
Please complete the Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology Customer Confirmation Form (attached) and contact your Distributor directly. All affected product and Customer Confirmation Form must be returned through the Distributor.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

Sincerely,



Diana Teo  
Quality System Manager SEA  
Medtronic

Attachment A



Lot number

Item code



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**Customer Confirmation Form  
Medical Device Recall**

**Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology**

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	Name:
	E-mail:
Address:	Phone:
Telephone no:	
Fax no:	
E-mail:	

**Even if you have no affected stock to returned, please acknowledge this form and return to your local Medtronic contacts stated above**

Please tick (either one) only:

- No, no affected inventory to be returned.
- Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	QTY (Each)

**I acknowledge receipt of the Covidien EEA™ Hemorrhoid and Prolapse Stapler Set with DST Series™ Technology recall notification dated 10 April 2018, and understand the recall instructions provided.**

Name: \_\_\_\_\_ (print) Signature: \_\_\_\_\_ Stamp: \_\_\_\_\_ Date: \_\_\_\_\_