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**URGENT MEDICAL DEVICE RECALL**  
**Endo GIA™ Ultra Universal Stapler Handles**

December 2, 2015

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

**Please forward this communication to all surgeons, surgical personnel and any other potential users of the product.**

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of Covidien Endo GIA™ Ultra Universal Stapler Handles. This voluntary recall is being conducted following customer reports of instruments failing to fire or partially firing and reports of the instrument articulating lever disengaging during use. If the instrument fails to fire or partially fires, or if the articulating lever disengages, the surgeon may be required to replace the device to continue the procedure. No patient injuries related to these issues have been reported. The complaint rate for the instrument failing to fire or partially firing for the affected lots is 0.04% and the complaint rate for the articulating lever disengaging is .006%.

Medtronic is requesting that you quarantine any remaining inventory of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed Endo GIA™ Ultra Universal Stapler Handles to other persons or facilities, please promptly forward the information from this letter to those recipients. All affected units must be returned.

This voluntary recall affects the lots listed in Attachment B for the three item codes listed below.

Item Code	Product Description	Lot Numbers
 EGIAUSHORT	Endo GIA™ Ultra Universal Short Stapler Handle	See Attachment B
 EGIAUSTND	Endo GIA™ Ultra Universal Standard Stapler Handle	See Attachment B
 EGIAUXL	Endo GIA™ Ultra Universal XL Stapler Handle	See Attachment B

**Required Actions:**

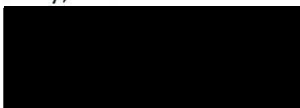
1. Please quarantine and discontinue use of the affected item codes and lots listed on Attachment B.
2. Please complete the attached Recalled Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick "No affected inventory to be returned" 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 Endo GIA™ Ultra Universal Stapler Handles Recalled Product Return 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 Endo GIA™ Ultra Universal Stapler Handles Recalled Product Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return 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.

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.

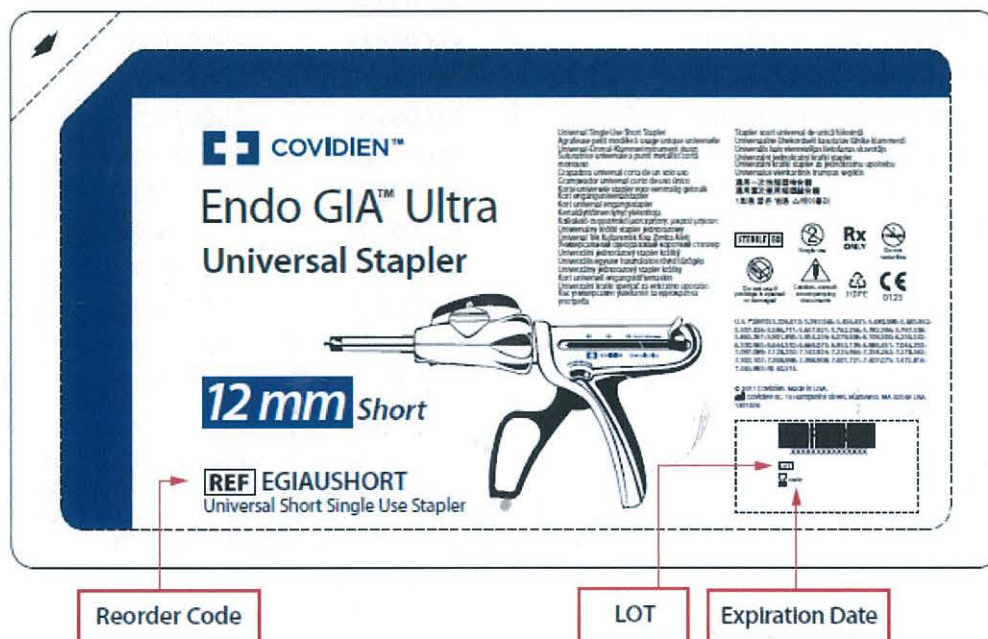
Sincerely,



Gilbert Penaflor  
QA Manager, South East Asia  
Medtronic




## Attachment A

Distinguish affected product by Item Code and Lot Number.





**Attachment B: Affected Lot List**

Item Code	Product Description		
EGIAUSHORT	Endo GIA™ Ultra Universal Short Stapler Handle 		
RANGES OF LOT NUMBERS (all numbers within each range are affected)		INDIVIDUAL LOT NUMBERS (in addition to ranges shown at left)	
Lot # starting with P3C through P5B0289X P5C0196X through P5C0197X P5C0304X through P5C0307X P5C0796X through P5C0798X P5D0049X through P5D0051X P5D0146X through P5D0148X P5E0261X through P5E0262X P5F0158X through P5F0161X		N3F0260RX N3F0266RX N3F0267RX P5C0201X P5D0538X P5E0680X P5E0682X P5E0686X	P5E0760X P5E0762X P5E0765X
Item Code	Product Description		
EGIAUSTND	Endo GIA™ Ultra Universal Standard Stapler Handle 		
RANGES OF LOT NUMBERS (all lot numbers within each range are affected)		INDIVIDUAL LOT NUMBERS (in addition to ranges shown at left)	
Lot # starting with P3C through P5B0521X P5D0410X through P5D0411X P5D0823X through P5D0829X P5E0080X through P5E0082X P5E0317X through P5E0320X P5E0322X through P5E0324X P5F0001X through P5F0002X		P5C0239X P5C0241X P5C0508X P5C0510X P5C0512X P5C0597X P5C0599X P5C0601X P5C0603X P5C0684X P5C0803X P5C0805X P5C0807X	P5D0067X P5D0069X P5D0073X P5D0170X P5D0413X P5D0415X P5D0417X P5D0419X P5D0447X P5D0623X P5D0624X P5D0626X P5D0628X  P5D0630X P5E0525X P5F0004X P5F0006X P5F0008X P5F0010X P5F0014X P5F0017X P5F0019X P5F0021X P5F0213X P5F0217X
Item Code	Product Description		
EGIAUXL	Endo GIA™ Ultra Universal XL Stapler Handle 		
RANGES OF LOT NUMBERS (all lot numbers within each range are affected)		INDIVIDUAL LOT NUMBERS (in addition to ranges shown at left)	
Lot # starting with P3C through P5B0454X P5C0152X through P5E0450X		P5B0468X	

## **RECALLED PRODUCT RETURN FORM**

Endo GIA™ Ultra Universal Stapler Handles

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Covidien Contact Details
Hospital / HCP:	By E-mail:
Address:	By Post:
Telephone no:	
Fax no:	
E-mail:	

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	Expiry Date	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Recall regarding Endo GIA™ Ultra Universal Stapler Handles by signing below:

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

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