

URGENT FIELD SAFETY NOTICE
Endo GIA™ Ultra Universal Stapler Handles

December XX, 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 recalling specific item codes and production lots of Covidien Endo GIA™ Ultra Universal Stapler Handles. This Field Safety Corrective Action (FSCA) 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 have been reported related to these issues. The complaint rate for the instrument fails to fire or partially fires 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 FSCA 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
 EGIAUXXL	Endo GIA™ Ultra Universal XL Stapler Handle	See Attachment B

Required Actions:

1. Please quarantine and discontinue use of the affected item codes listed above.
2. Please return affected product as follows:

	Customer with inventory:	Customer with Zero Inventory	Where to send the completed form
Purchased DIRECTLY from Medtronic	<p>Please complete the attached Returns Verification Form in its entirety and e-mail it to <local RA Mailbox> or fax to XXX.</p> <p>Upon receiving your form, Customer Service will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.</p>	Complete form & 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 & contact your Distributor directly to arrange for return of product.	Complete form & 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

This action is being taken with the knowledge of the (Insert Local Competent Authority Name).

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information stated above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at (xxx-xxx-xxx).

Sincerely,


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 Surgical Innovations
 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 lot 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 attleft)	
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 attleft)	
Lot # starting with P3C through P5B0454X P5C0152X through P5E0450X		P5B0468X	