Medtronic

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URGENT MEDICAL DEVICE RECALL
Covidien Endo GIA™ Black Radial Reload with Tri-Staple™ Technology

14 September 2017

Attention: Risk Management Director and O.R. Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling one production lot of its **Covidien Endo GIA™ Black Radial Reload with Tri-Staple™ Technology**

Issue Description:
This voluntary recall is being conducted following reports that the device cartridge disengaged during use due to manufacturing error. The use of products with this issue may result in the need for retrieval of a foreign body and/or incomplete deployment of the unit's staples resulting in a non-functional staple closure. No patient injury or impairment has been reported in relation to this issue.

This voluntary recall affects only the item code and lot listed below.

Item Code	Item Description	Affected Lot
EGIARADXT	Endo GIA™ Black Radial Reload with Tri-Staple™ Technology	N6L0351X

Medtronic requests that you quarantine and return any unused products of the item code and lot detailed below. Unused products from the affected item code and lot should be returned as described in the Required Actions section below. If you have distributed the Endo GIA™ Black Radial Reload 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.

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

  Please complete the Covidien Endo GIA™ Black Radial Reload with Tri-Staple™ Recall Return Form (attached) and return to your local Medtronic representative together with affect units if any.

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

  Please complete the Covidien Endo GIA™ Black Radial Reload with Tri-Staple™ Recall Return Form (attached) and contact your Distributor directly. All affected product and Recall Product Return Form must be returned through the Distributor.

This notification is being issued or will be notified to relevant regulatory bodies according to applicat 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 yc local Medtronic representative.

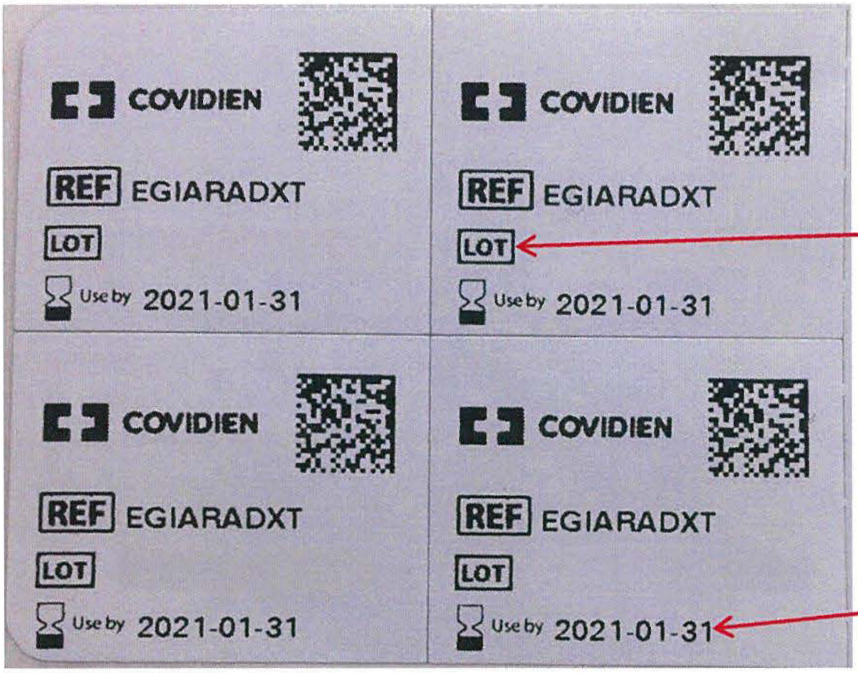
We appreciate your attention to this matter and apologize for any inconvenience this issue may ha caused.

Sincerely,

[redacted]

Diana Teo
QA Supervisor
Medtronic

Attachment A



Lot number

Expiration date

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RECALLED PRODUCT RETURN FORM
Covidien Endo GIA™ Black Radial Reload with Tri-Staple™ Technology

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

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

Even if you have no affected stock to returned, please complete this form and table; 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 have read and understand the instructions provided and acknowledge receipt of the Covidien Endo GIA™ Black Radial Reload with Tri-Staple™ Technology recall notification dated 14 September 2017 by signing below:

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____