

MEDICAL DEVICE RECALL LETTER

Endo GIA™ Auto Suture™ Universal Articulating Loading Unit – Lot numbers beginning with “H” Only

January 28, 2015

Attention: Risk Management Director and OR Materials Management

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

Dear Valued Customer:

Covidien Surgical Solutions is voluntarily recalling certain production lots of Endo GIA™ Auto Suture™ Universal Articulating Loading Units. These specific lots, beginning with the prefix “H”, contain modifications to the device that did not receive required country-specific regulatory authorization for distribution. The modifications to these devices do not pose any risk to your patients or clinicians. All other production lots of the product codes listed below have received the required regulatory authorization and are not affected by this field action.

The Endo GIA™ Auto Suture™ Universal Articulating Loading Units are intended for use in abdominal, gynecologic, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

This voluntary recall is limited to the product codes and lot numbers listed below. No other product codes or lot numbers are affected.

Product Code	Product Description	Lot Number Prefix
030455	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 45 mm-3.5 mm	H3K, H3L, H3M, H4C, H4D
030456	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 45 mm-4.8 mm	H3K, H4C, H4D, H4E
030458	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 60 mm-3.5 mm	H3F, H3K, H3L, H3M, H4A, H4B, H4C, H4F
030459	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 60 mm-4.8 mm	H3F, H3J, H3K, H4A, H4E, H4F

REQUIRED ACTIONS:

1. Please quarantine and discontinue use of the affected devices.

2. Please return affected product as follows:

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

Please complete the Endo GIA™ Auto Suture™ Universal Articulating Loading Units Recalled Product Return Form and fax it to the number stated on the form. If you do not have any units in your inventory, simply return the form indicating you have zero (0) units. Upon receiving your form, Customer Service will contact you to organize the return of your product. You will receive credit for returned product.

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


Please complete the Endo GIA™ Auto Suture™ Universal Articulating Loading Units Recalled Product Return Form (attached) and contact your Distributor directly. The completed form and all affected product must be returned through the Distributor.

- **ALL CUSTOMERS**

We ask that all customers reply to Covidien WHETHER OR NOT you have affected product at your site. Your response is vital to our monitoring of the effectiveness of this recall. Please complete the Endo GIA™ Auto Suture™ Universal Articulating Loading Units Recalled Product Return form and fax it to Covidien to the number stated on the form.

We apologize for this inconvenience and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your Covidien representative or Customer Service at XX.

Sincerely,



Theresa A. McGovern
Vice President Regulatory Affairs
Covidien

RECALLED PRODUCT RETURN FORM

Endo GIA™ Auto Suture™ Universal Articulating Loading Units

ALL CUSTOMERS PLEASE COMPLETE THIS FORM IN ITS ENTIRETY.

Date

Name of Person Completing this Form: Title:

Direct Phone #: Email:

Account Name: Covidien Account #:

Account Address:

City: State: Zip Code:

How did the account purchase this product? (Please check)

Direct from Covidien: From a Distributor:

Distributor Name:

Address:

City: State: Zip Code:

Return Goods Authorization (RGA) #: (please include once received from Customer Service)

No Inventory (Please check):

Product Code	Product Description	Lot Number	Quantity (Each)

I ACKNOWLEDGE RECEIPT OF THE Endo GIA™ Auto Suture™ Universal Articulating Loading Units RECALL NOTIFICATION DATED January XX, 2015, AND UNDERSTAND THE RECALL INSTRUCTIONS PROVIDED.

(SIGNATURE REQUIRED)

FIGURE 1:
