COVIDIEN

URGENT FIELD SAFETY NOTICE

Endo GIA™ AutoSuture™ Universal Loading Unit 30mm-2.0mm

February XX, 2013

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,

The purpose of this letter is to advise you that Covidien is conducting a Field Safety Corrective Action (FSCA) of four production lots of the Endo GIA™ AutoSuture™ Universal Loading Unit 30mm-2.0mm. The Endo GIA™ Universal staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis.

Covidien has received one report of an adverse event where a Single Use Loading Unit contained two staples loaded in each cartridge pocket. This condition may result in difficulty firing and removing the device from the application site, which may require medical intervention. Covidien has not received any reports of post-operative complications related to this condition.

This FSCA is limited to the material code and lot #'s identified below and does NOT affect any other lots of Covidien devices.

Product Code	Product Description	Lot Number
030450	Endo GIA™ AutoSuture™ Universal Loading Unit 30mm-2.0mm	N2F0563LX
		N2F0341LX
		N2F0725LX
		N2E0605LX

REQUIRED ACTIONS:

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

2. Immediately advise all Endo GIA™ AutoSuture™ Universal Loading Unit 30mm-2.0mm users of this FSCA.

3. Please complete the attached Verification Form in its entirety. Fax the completed Form to the fax number or email address stated on the form. If you do not have any units in your inventory, simply return the Verification Form indicating you have zero (0) units.

4. Please return affected product as follows:

    a. Customers, who purchased product directly from Covidien, please complete the form and return it. Upon receiving your form, Customer Service will be contacting you to organize the return of your products. You will receive credit for returned products.

b. Distributors that further distributed product from the affected lots must forward this notification to their customers. Your customers must complete the verification form and return the completed form with affected units directly to their Distributor.

c. If you purchased product from a distributor please complete the verification form (attached) and contact your Distributor directly. The completed form and all affected units must be returned through the Distributor.

5. Please complete the Endo GIA™ AutoSuture™ Universal Loading Unit 30mm-2.0mm verification form and return to Covidien via the instructions provided. We ask that you reply to Covidien **WHETHER OR NOT** you have affected product at your site. Your response is vital to monitoring the effectiveness of this FSCA.

If you have any questions or concerns regarding the return process or product related questions, please do not hesitate to contact your Covidien representative at [add local contact number].

This action is being taken with the knowledge of the [add local Competent Authority]. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We know you share our interest in the primacy of patient safety and we sincerely apologize for any inconvenience this may cause. Thank you for your business and continued support.

Robert Jamieson
Covidien Advanced Surgical Technologies
Vice President, Quality Assurance