COVIDIEN

15 May 2012

Attention: Operating Room Director/ Materials Management

Dear Customer,

COVIDIEN (formerly United States Surgical, a division of Tyco Healthcare Group, L.P.) is conducting a **VOLUNTARY RECALL** of various production lots of ROTICULATOR™ Single Use Stapler.

This voluntary recall is being conducted due to the potential for the sterility barrier to be compromised. The use of products with this condition may result in a potentially increased risk for infection.

Please note the affected product reference numbers and descriptions are listed below.

REF #	PRODUCT DESCRIPTION
017612	ROTICULATOR™ 55-3.5 Single Use Stapler
017614	ROTICULATOR™ 55-4.8 Single Use Stapler
017615	ROTICULATOR™ 30-3.5 Single Use Stapler
017617	ROTICULATOR™ 30-4.8 Single Use Stapler
017619	ROTICULATOR™ 30-V3 Single Use Stapler

LOT #'s BEGINNING WITH THE FOLLOWING LETTER/NUMBER COMBINATIONS ARE AFFECTED AND MUST BE RETURNED.

P7E	**P8B**	**P8L**	**P9H**	**P0E**	**P1B**	**P1L**
P7F	**P8C**	**P8M**	**P9J**	**P0F**	**P1C**	**P1M**
P7G	**P8D**	**P9A**	**P9K**	**P0G**	**P1D**	**P2A**
P7H	**P8E**	**P9B**	**P9L**	**P0H**	**P1E**	**P2B0153X**
P7J	**P8F**	**P9C**	**P9M**	**P0J**	**P1F**	
P7K	**P8G**	**P9D**	**P0A**	**P0K**	**P1G**	
P7L	**P8H**	**P9E**	**P0B**	**P0L**	**P1H**	
P7M	**P8J**	**P9F**	**P0C**	**P0M**	**P1J**	
P8A	**P8K**	**P9G**	**P0D**	**P1A**	**P1K**	

Also Best Practice Kits Ref #'s: 00Z0800, 00Z0976, 00Z1401, 00Z1407, 00B0117, 00B0122

NOTE: THE SPECIFIC LOT NUMBERS LISTED BELOW AND LOT NUMBERS ENDING IN **""RMX"** and **"RRMX"** ARE ***NOT*** AFFECTED BY THIS RECALL AND ARE ACCEPTABLE FOR USE. **P2A0194XR, P2B0488XR, P2B0153XR**

COVIDIEN PRIVATE LIMITED
CO. REGISTRATION NO: 199800515M

103 PENANG ROAD
VISIONCREST COMMERCIAL
#10-01
SINGAPORE 238467

65-6482-0100[T]
65-6482-0300 [F]

COVIDIEN

REQUIRED ACTIONS:

1. Please immediately identify and quarantine all affected inventory.
   NOTE: Units from the affected lots may have been incorporated into Covidien BEST PRACTICE™ KITS. If you have purchased BEST PRACTICE™ KITS, please evaluate whether these kits contain units from the affected lots. All affected ROTICULATOR™ units must be returned.

2. Please complete the attached ROTICULATOR™ Single Use Stapler Recalled Product Return form in its entirety. If you do not have any units from the affected lots in your inventory, simply return the product return form indicating you have zero(0) unit and report to our local Covidien office.

3. Please return affected product to its invoicing entity as follows:

   a. Customers that received product directly from COVIDIEN, please return affected product to our local Covidien office with completed ROTICULATOR™ Single Use Stapler Recalled Product Return form.

   b. If you purchased product from a Distributor please complete the ROTICULATOR™ Single Use Stapler Recalled Product Return form and contact your Distributor directly. The completed form and all affected units must be returned through the Distributor.

This voluntary recall is limited to the material codes and lot #'s beginning with the letter/number combinations identified and does ***NOT*** affect any other lots of Covidien devices. This voluntary recall is being conducted with the knowledge of the FDA.

We ask that you 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.

We apologize for any inconvenience this may have caused 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.

Sincerely,

Mi Youn Chang
RA Director - Korea & SEA

Attachment A: ROTICULATOR™ Single Use Stapler Recalled Product Inventory Form

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Attachment A

ROTICULATOR™ Single Use Stapler Recalled Product Return form

Product REF #'s:

017612	ROTICULATOR™ 55-3.5 Single Use Stapler
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P7G	**P8D**	**P9A**	**P9K**	**P0G**	**P1D**	**P2A**
P7H	**P8E**	**P9B**	**P9L**	**P0H**	**P1E**	**P2B0153X**
P7J	**P8F**	**P9C**	**P9M**	**P0J**	**P1F**	
P7K	**P8G**	**P9D**	**P0A**	**P0K**	**P1G**	
P7L	**P8H**	**P9E**	**P0B**	**P0L**	**P1H**	
P7M	**P8J**	**P9F**	**P0C**	**P0M**	**P1J**	
P8A	**P8K**	**P9G**	**P0D**	**P1A**	**P1K**	

Also Best Practice Kits Ref #'s: 00Z0800, 00Z0976, 00Z1401, 00Z1407, 00B0117, 00B0122

Date: _____

Name of Person Completing form: _____ Title: _____

Direct Phone #_____ Email: _____

Account Name: _____ Covidien Account number: _____

Account ddress: _____

City: _____ State: _____ Zip code: _____

Attachment A

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

_____Direct from Covidien _____ From a Distributor (*Fill in your distributor details*)

Distributor Name:_____

Address:_____

City: _____State:_____Zip Code:_____

1. Complete the attached inventory sheet by writing the product reference #, lot # and total number of units being returned from each lot. Return the completed form with the affected product(s).

2. If you do not have any of the affected inventory, please check, **"No Inventory"** below

   No Inventory: _____ (Please Check)

PRODUCT REFERENCE NUMBER	LOT NUMBER	TOTAL UNITS