Medtronic
60 Middletown Avenue
North Haven, CT 06473
www.medtronic.com

URGENT MEDICAL DEVICE RECALL

March 13, 2019

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of the

Covidien Endo Clinch™ II and Endo Grasp™ Auto Suture™ graspers 5mm.

Issue Description:

This voluntary recall is being conducted following a review of production records which indicate that the sterilization method used for these lots were not consistent with the labeling and the approved sterilization method. These products are labeled as sterilized with gamma radiation and in some cases, the devices were subjected to re-sterilization with ethylene oxide or a repeat gamma sterilization cycle. While re-sterilization with ethylene oxide does not impact device performance, it is not consistent with the product labeling. The use of products that have been re-sterilized using a gamma sterilization method may result in an increased potential for device failure and disengaged components. A resultant delay in treatment may occur while a replacement device is obtained and disengaged components are retrieved. The sterility of all affected devices is intact. There have been no complaint reports received for any of the affected lots.

This voluntary recall affects only the item codes and lots listed below.

Item Code	Description	Affected Lot Numbers		
174317	Covidien Endo Clinch™ II Auto Suture™ Grasper 5mm	P8D1333PRX	P8E1189PRX	P8F1239PRX
		P8D1334PRX	P8E1269PRX	P8F1307PRX
		P8D1614PRX	P8E1271PRX	P8F1448PRX
		P8D1615PRX	P8E1272PRX	P8F1452PRX
		P8D1616PRX	P8F0008PRX	P8F1480PRX
		P8E1143PRX	P8F1238PRX	P8F1545PRX
173030	Covidien Endo Grasp™ Auto Suture™ Grasper 5mm	P8D1335PRX	P8D1336PRX	P8D1605PRX

We request that you quarantine and return any unused products of the above item codes and production lots. Unused products from the affected item codes should be returned as described in the Required Actions section below. If you have distributed the Endo Clinch™ II or Endo Grasp™ Auto Suture™ graspers 5mm 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.

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Required Actions:

1. Please immediately quarantine and discontinue use of the affected item codes and lots listed above.
2. Please return affected product as indicated below.
3. If you have distributed the Endo Clinch™ II or Endo Grasp™ Auto Suture™ graspers 5mm listed above, please promptly forward the information from this letter to those recipients.
4. Complete the Recalled Product Return Form **even if you do not have inventory**.

	Customer with inventory	**Customer with zero inventory**	**Where to send the completed form**
Purchased **directly** from Medtronic	Complete the Recalled Product Return Form and email to: feedback.customerservice@covidien.com fax to: 800-895-6140 Ship affected product with RGA# provided by Customer Service to: **Medtronic** **Attn: Field Returns** **195 McDermott Road** **North Haven, CT 06473 USA**	Complete form and check the box indicating "no inventory"	Fax to 800-895-6140 or email feedback.customerservice@covidien.com **Exception:** Customers with zero inventory, fax to 203-492-7719 or email to GMBFCAMITG@Medtronic.com
Purchased from a **distributor**	Complete **all** fields on the form and contact your distributor directly to arrange for return of product	Complete form and check the box indicating "no inventory"	Fax to 203-492-7719 or email GMBFCAMITG@Medtronic.com

This action is being taken with the knowledge of the FDA. We request that you contact us if you experienced quality problems or adverse events.

- Email Medtronic Post Market Vigilance at: quality.assurance@medtronic.com

The FDA can be contacted to report any adverse events experienced with the use of these products:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or Call FDA 1-800-332-1088

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Customer Service at 800-962-9888, option 2.

[redacted]

J. Bryan Dannettell
Vice President, Quality
Surgical Innovations
Minimally Invasive Therapies Group

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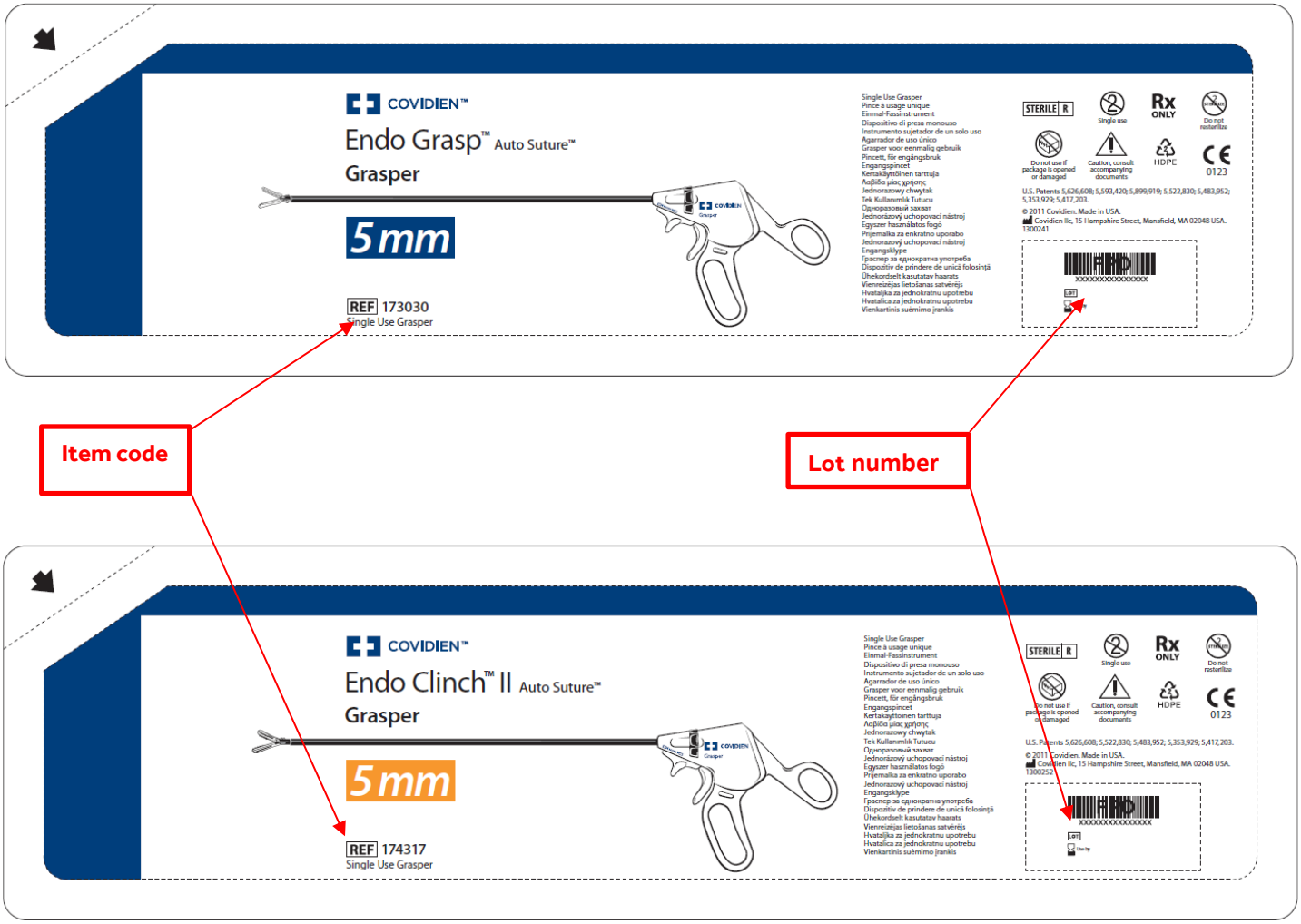
Attachment A



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RECALLED PRODUCT RETURN FORM

Covidien Endo Clinch™ II and Endo Grasp™ Auto Suture™ Graspers 5mm

PLEASE COMPLETE THIS FORM

Customers must complete the form even if you do not have inventory.

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email

How did the account purchase this product? (Please complete **ONLY** A or B)

Direct from Medtronic (Complete A): **From a Distributor (Complete B):**

A. Direct Customers:

Account Name:

Account #:

Account Address:

City:

State: Zip Code:

B. From a Distributor:

Distributor:

Customer Information:

Customer Name:

Address:

City:

State: Zip:

RETURN INVENTORY TO: Medtronic, Attn: Field Returns Dept. 195 McDermott Road North Haven, CT 06473 USA

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

No Inventory (Please check):

Item Code	Lot Number	Qty	Case or Each

I acknowledge receipt of the Endo Clinch™ II and Endo Grasp™ Auto Suture™ grasper 5mm recall notification dated March 13, 2019 and understand the recall instructions provided.

(Signature Required)

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:
Product purchased directly from Medtronic: feedback.customerservice@Covidien.com or fax to (800) 895-6140.
Product purchased through distributor: GMBFCAMITG@Medtronic.com or fax it to (203) 492-7719.