ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT: FIELD SAFETY NOTICE

ECHELON FLEX™ ENDOPATH® 60mm Staplers
Product Codes: PSEE60A, PLEE60A
(Multiple Lot Numbers) – Voluntary Product Recall

October 3, 2019

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Our records indicate that you may have ordered or received product subject to this recall. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ECHELON FLEX™ ENDOPATH® 60mm Staplers.**

Ethicon has initiated a voluntary recall of **specific product lots** of **ECHELON FLEX ENDOPATH 60mm Staplers**, as listed **in table 1**, were distributed in Saudi Arabia and Kuwait. Ethicon identified through manufacturing process inspections there is a possibility some devices may contain an out of specification condition which could lead to malformed staples. We have identified the root cause and we have implemented corrective actions to address the issue.

EFFECTIVE IMMEDIATELY–DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODE / LOT:

Table 1 – Product Subject to this Field Safety Corrective Action

PRODUCT CODE	PRODUCT LOT	DESCRIPTION
PSEE60A	T94008	ECHELON FLEX™ Powered Plus ENDOPATH® 60mm Stapler – 440mm shaft
	T93Z5X	
	T9400D	
	T9405W	
PLEE60A	T93Z1G	ECHELON FLEX™ Powered Plus ENDOPATH® 60mm Stapler – 340mm shaft
	T93Z2W	
	T93Z2X	
	T93Z5T	
	T93Z5W	
	T93Z75	
	T9405L	

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Ethicon identified through manufacturing process inspections that a small percentage (<1%) of devices from impacted lots may contain an out of specification anvil component within the jaw of the device. A stop shipment for **product lots** subject to this recall (removal) was initiated. The out of specification condition may lead to malformed staples, which can compromise staple line integrity. If the staple line is compromised, there is a potential risk of prolonged surgery, postoperative anastomotic leak, hemorrhage, hemorrhagic shock additional surgical intervention, or death.

Health care practitioners who have treated patients using **ECHELON FLEX ENDOPATH 60mm Staplers** should follow those patients post-operatively in the usual manner with no additional action required. This voluntary recall does NOT affect any other product codes or lots for ECHELON FLEX ENDOPATH 60mm Staplers.

Refer to Attachment 1 for assistance in identifying the **product lot** subject to this voluntary recall.

Our records indicate that you may have ordered or received product subject to this recall. The domestic dates of distribution for affected products were from August 1, 2019 - August 15, 2019.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL (Removal):

Product subject to the recall (removal) in your inventory can be identified by product code and lot number (see product code listing above). All unused ECHELON FLEX ENDOPATH 60mm Staplers product subject to this recall (removal) are required to be returned. The product code and lot number can be determined by using the Product Identification Tool attached at Attachment 1.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have **product lots** subject to this recall (removal) on hand and quarantine such product(s).

2. Remove the **products** subject to this voluntary recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.

3. If any **product lots** subject to this recall (removal) have been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this Field Safety Notice when communicating.

4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and email it to [Suzan AlDawalibi : Saldawal@its.jnj.com] within three (3) business days. **Please return the BRF even if you do not have product subject to this recall (removal)**.

5. Keep this notice visibly posted for awareness until all product subject to this recall has been returned. While processing your returns, please maintain a copy of this notice with the product subject to this recall (removal) and keep a copy for your records.

6. Customers are required to return unused impacted **ECHELON FLEX ENDOPATH 60mm Staplers** subject to this recall that are in their inventory immediately. To receive replacement product, customers must return product subject to this recall ***by December 31, 2019*, any *non-affected product and any product returned after the date specified will not be replaced.***

7. To return product lots subject to this recall, photocopy the completed BRF, place it in the box with the product,

If you require any assistance with returning product lots subject to this recall, please contact [Suzan AlDawalibi : Saldawal@its.jnj.com]

We recognize the Field Safety Corrective Action of the **ECHELON FLEX ENDOPATH 60mm Staplers** may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this Field Safety Corrective Action or to report any customer complaints, please contact [suzan aldawalibi: saldawal@its.jnj.com]

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, or your National Health Authority. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative.

Attachments:
Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form

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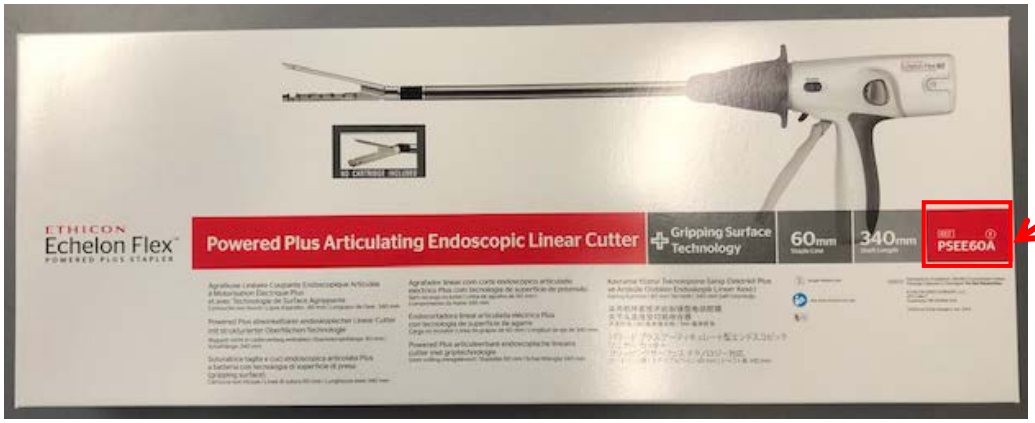
ATTACHMENT 1: Product Identification Tool for ECHELON FLEX ENDOPATH 60mm Staplers

This tool will help customers identify the impacted product subject to this recall. This document applies to the sales unit carton and Tyvek for specific product codes and lots for ECHELON FLEX ENDOPATH 60mm Staplers.

While the labeling below is an example and is representative of the impacted product code/lot, ECHELON FLEX ENDOPATH 60mm Staplers within each product family have very similar labeling and the product codes and lot numbers can be identified using the same images below.

SINGLE UNIT CARTON (CONTAINING (1) SEALED TYVEK TRAY)

FRONT OF SINGLE UNIT CARTON



LABEL ON SINGLE UNIT CARTON

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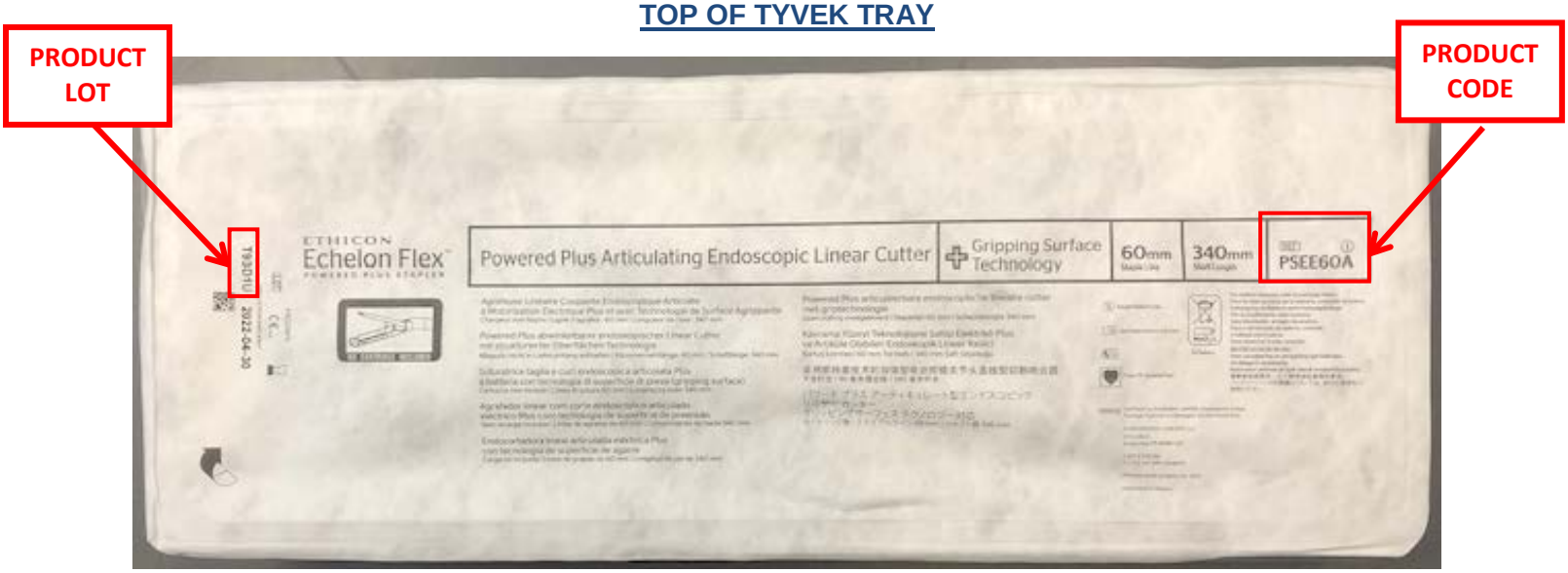
TYVEK TRAY (CONTAINING (1) ECHELON FLEX ENDOPATH 60mm Stapler)

TOP OF TYVEK TRAY



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ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this Field Safety Notice is requested. Please complete and send the form to [Suzan AL Dawalibi : Saldawal@its.jnj.com] **within 3 business days, even if you do not have product subject to this Field Safety Corrective Action to return.**

Product Inventory – *please check one:*

☐ **We have NO ECHELON FLEX ENDOPATH 60mm Staplers subject to this Field Safety corrective Action.**

☐ **We have ECHELON FLEX ENDOPATH 60mm Staplers subject to this Field Safety corrective Action and are returning the following products:**

PRODUCT CODE	PRODUCT LOT	Number of Products available for return (Eaches)

Account Name_____

Account Address_____

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Replacement Product Shipping Address (If different from above):	
Signed*: *Your signature provides confirmation that you have received and understood this notification	
Your comments are welcome.	