

## URGENT: FIELD SAFETY NOTICE

### ECHELON FLEX™ Powered Plus Stapler: Product Code PSEE60A, Lot U94V47 – Voluntary Product Recall (Removal) –

[Insert Date]

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

Ethicon has initiated a voluntary medical device recall (removal) due to the product mix involving one (1) lot of ECHELON FLEX™ Powered Plus Stapler, Product Code PSEE60A, Lot U94V47. A small portion of the ECHELON FLEX™ Powered Plus Stapler lot which is labeled on the package as 60mm contains ECHELON FLEX™ Powered Plus Stapler 45mm devices. The length is correctly marked on the 45mm ECHELON FLEX™ Powered Plus Stapler within the package, and the issue is easily detectable by the user. 45mm staplers are not compatible with 60mm reloads, so this issue may lead to user inconvenience, including necessity to obtain additional product, potentially resulting in a slight surgical delay. We apologize for any inconvenience this may have caused.

**Ethicon has not received any reports of Adverse Events or Injuries related to this issue, and there is no anticipated patient safety impact.** We have identified the root cause and are implementing corrective actions to address the issue.

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHICON LINEAR CUTTERS.**

**EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODE/ LOT. REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS.**

Table 1: Impacted ECHELON FLEX™ Powered Plus Stapler Details

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	EXP DATE	DISTRIBUTION DATES	GTIN / PRIMARY DI NUMBER	DESCRIPTION / SIZE
ECHELON FLEX™ Powered Plus Stapler	PSEE60A	U94V47	July 31, 2023	August 28, 2020 – September 16, 2020	10705036014607	Powered Plus Articulating Endoscopic Linear Cutter, +Gripping Surface Technology, 60mm Staple Line, 340mm Shaft Length

This recall (removal) does NOT affect any other product codes or lots of ECHELON FLEX™ Powered Plus Staplers.

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Table 2 has procedure pack codes and lot numbers that contain ECHELON FLEX™ Powered Plus Staplers subject to this recall.

Table 2: Procedure Packs with ECHELON FLEX™ Powered Plus Stapler Details

<b>PROCEDURE PACK CODE</b>	<b>PROCEDURE PACK LOT</b>	<b>PROCEDURE PACK CODE</b>	<b>PROCEDURE PACK LOT</b>	<b>PROCEDURE PACK CODE</b>	<b>PROCEDURE PACK LOT</b>
CKMULT00260NS	10211415	LCOL202B	10216691	LSR218B	10215394
CKMULT00260NS	10211419	LCOL202B	10216695	LSR218B	10215397
CKMULT00260NS	10211421	LCOL223	10215007	LSR218B	10215398
CKMULT00260NS	10211423	LCOL223	10215008	LSR344	10214537
CKMULT00260NS	10211427	LCOL223	10215014	LSR344	10214538
CKMULT00260NS	10211428	LCOL223	10215020	LSR344	10214554
CKMULT00260NS	10211437	LCOL59P	10216382	LSR344	10214557
CKMULT00260NS	10211438	LCOL59P	10216397	LSR344	10214561
CKMULT00260NS	10211441	LGAS11	10216688	LSR344	10214564
CKMULT00260NS	10211443	LGAS11	10216689	LSR344	10214550
CKMULT00260NS	10211432	LGAS11	10216687	LSR344	10214562
CKMULT00260NS	10211435	LGBP347	10216118	LSR344	10214569
CKMULT00261NS	10211364	LGBP385P	10215083	LSR344	10214576
CKMULT00261NS	10211367	LGBP385P	10215085	LSR344	10214585
CKMULT00261NS	10211369	LGBP385P	10215090	LSR344	10214551
CKMULT00261NS	10211374	LGBP385P	10215093	LSR346	10214462
CKMULT00261NS	10211376	LGBP557	10214611	LSR346	10214467
CKMULT00261NS	10211379	LGBP557	10214616	LSR363B	10215352
CKMULT00264	10211387	LGBP557	10214622	LSR363B	10215307
CKMULT00264	10211389	LGBP557	10214627	LSR363B	10215332
CKMULT00264	10211390	LGBP723	10215338	LSR363B	10215341
CKMULT00264	10211391	LGBP723	10215434	LSR363B	10215350
CKMULT00264	10211392	LGBP723	10215435	LSR363B	10215367
CKMULT00264	10211393	LSR130P	10216775	LSR363B	10215382
LCOL138	10214286	LSR130P	10216779	LSR363B	10215396
LCOL138	10214292	LSR130P	10216781	LSR397B	10214586
LCOL138	10214296	LSR130P	10216786	LSR397B	10214591
LCOL138	10214301	LSR130P	10216792	LSR397B	10214595
LCOL148	10214276	LSR130P	10216799	LSR397B	10214599
LCOL148	10214285	LSR141B	10215117	LSR397B	10215127
LCOL148	10214293	LSR141B	10215122	LSR397B	10215131
LCOL148	10214300	LSR141B	10215143	LSR397B	10215134
LCOL158	10215079	LSR141B	10215194	LSR397B	10215136
LCOL158	10215087	LSR141B	10215177	LSR398	10214801
LCOL158	10215094	LSR141B	10215180	LSR398	10214804
LCOL158	10215096	LSR141B	10215189	LSR398	10214805
LCOL158	10215098	LSR194P	10215399	LSR398	10214806
LCOL158	10215102	LSR194P	10215404	LSR398	10214807
LCOL176	10214157	LSR194P	10215407	LSR398	10214808
LCOL176	10214163	LSR194P	10215411	THORAX23	10215337
LCOL202B	10215034	LSR197B	10215187	THORAX23	10215351
LCOL202B	10215038	LSR197B	10215188	THORAX23	10215357
LCOL202B	10215058	LSR218B	10215373	THORAX23	10215364
LCOL202B	10215114	LSR218B	10215378		
LCOL202B	10216690	LSR218B	10215387		

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**ECHELON FLEX™ Powered Plus Stapler:** Product Code PSEE60A, Lot U94V47

**– Voluntary Product Recall (Removal) –**

### **IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL:**

Product subject to the recall in your inventory can be identified by product information described in Table 1 and Table 2. All unused ECHELON FLEX™ Powered Plus Stapler 60mm and Procedure Packs subject to this recall are required to be returned. Please utilize **Attachment 1** and **Attachment 2** for assistance in identifying the product lot subject to this recall.

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### **ACTION REQUIRED:**

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s).
2. Remove the product subject to this 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 subject to this action has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
4. Complete the Business Reply Form (BRF) (Attachment 3) confirming receipt of this notice and return to **[Insert Affiliate Information]** within three (3) business days. Please return the BRF even if you do not have product subject to this recall.
5. Follow instructions in the letter and immediately return any inventory of ECHELON FLEX™ Powered Plus Stapler and Procedure Packs referenced in Table 1 and Table 2. We request that product subject to this recall be returned no later than September 10, 2021 to **[Insert Affiliate Information]**. Any non-affected product and any product returned after the date specified will not receive replacement.
6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to **[Insert Affiliate Information]**. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.

At Ethicon, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this voluntary product recall or require any assistance with returning product, please contact **[Insert Affiliate Information]**.

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: Procedure Pack Identification Tool
- Attachment 3: Business Reply Form (BRF)

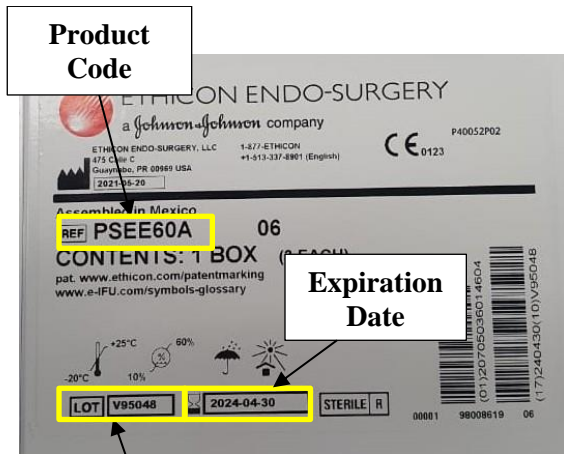
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**ECHELON FLEX™ Powered Plus Stapler: Product Code PSEE60A, Lot U94V47**  
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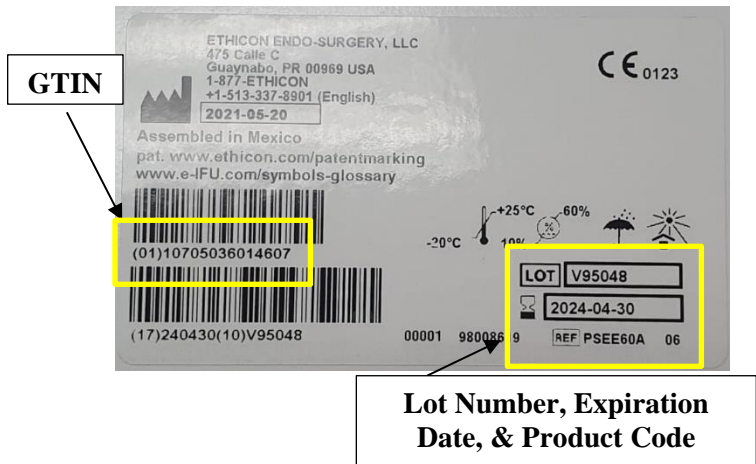
## Attachment 1: Product Identification Tool

This tool will help customers identify the location of the product name, product code, GTIN, lot number, and expiration date of ECHELON FLEX™ Powered Plus Stapler, subject to this recall by using the packaging labels. This document applies to Product Code PSEE60A, Lot U94V47.

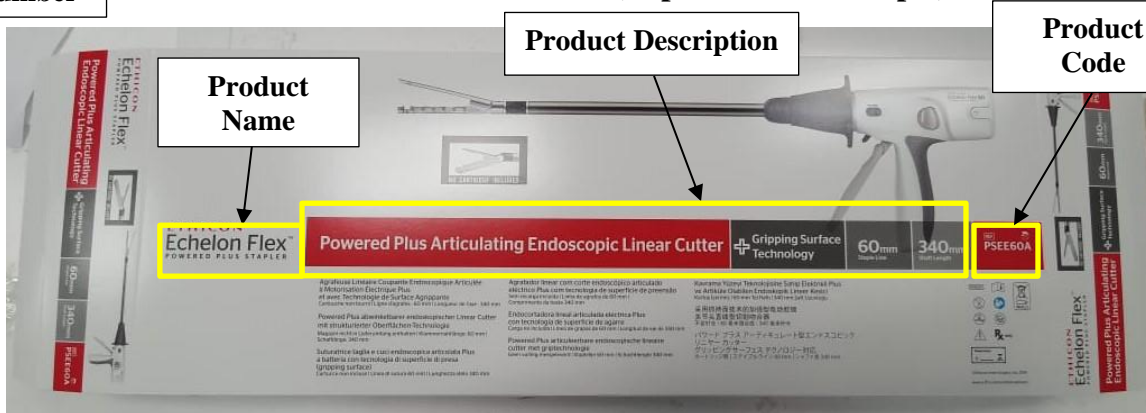
### Sales Unit Box (Representative Sample)



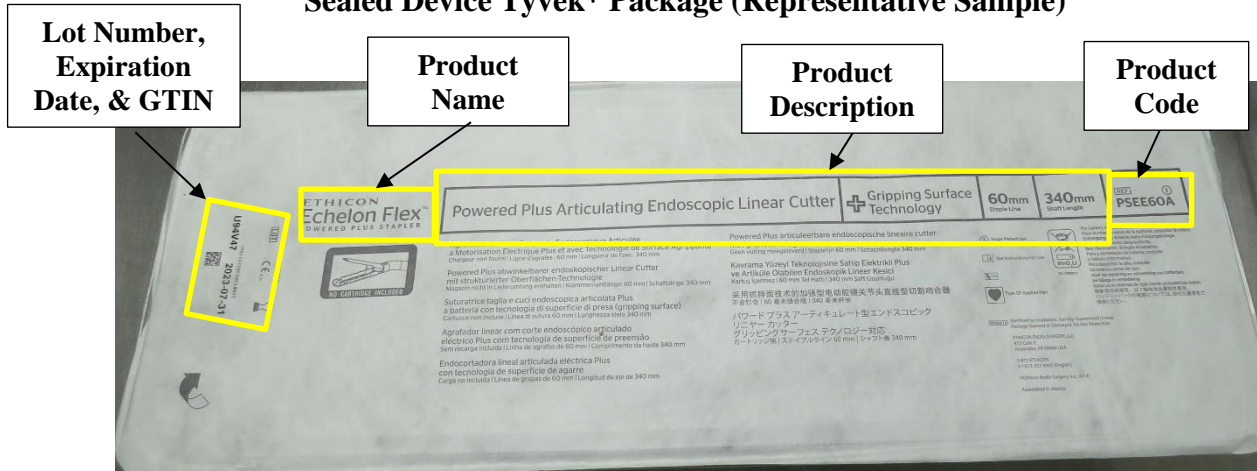
### Individual Unit Box - Back (Representative Sample)



### Individual Unit Box - Front (Representative Sample)



### Sealed Device Tyvek\* Package (Representative Sample)



\*Tyvek is a trademark of E.I. du Pont de Nemours and Company or its affiliates

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## Attachment 2: Procedure Pack Identification Tool




This tool will help customers identify the location of Product Code and lot number of Procedure Packs subject to this recall by using the Procedure Pack packaging labels.


### Procedure Pack Box (Representative Sample)

Product Code

REF LCOL176 LAPAROSCOPIC COLON PACK

KIT POUR COLON LAPAROSCOPIQUE      SET AANPANDOPHWE EFEMBRACHE FAKEDSE ENTERY  
 BEHANDLINGSET FÜR LAPAROSKOPISCHE KOLON-OPERATION      ADJUNAÇÃO DE PRODUTO PARA COLON LAPAROSCÓPICO  
 KIT FÜR LAPAROSKOPIAL COLON      COLAJITO PARA COLON LAPAROSCÓPICO  
 PAKKET VOOR LAPAROSKOPISCHE COLONPROCEDURES

QTY	REF		
1	PSEE60A CE MD		<b>ECHELON FLEX™ Powered Plus Articulating Endoscopic Linear Cutter</b>   with Gripping Surface Technology   80mm Staple Line   340mm Shaft Length Agrețoare liniară articulantă endoscopică articulată ECHELON FLEX™ Plus a presiunii electrice   este tehnologie de suprafață agriștoare   Lungimea liniei agrisă 80mm   Lungimea de la capăt 340mm Powered Plus articulating endoscopic Linear Cutter   Endoscopic Surface Technology   80mm Staple Line   Length 340mm Endoscópica articuladora lineal articulada Powered Plus   Con tecnología Gripping Surface   Línea de sutura 80mm   Longitud de la punta 340mm PowerPlus liniea endoscópica articulată electrică   cu tehnologie de suprafață de agrișă   Linia de grișuri 80mm   Lungimea de la capăt 340mm Endoscópica lineal articuladora articulada eléctrica Plus   con tecnología de superficie de agarre   Línea de grietas de 80mm   Compromiso de la punta de 340mm
1	CDH29P CE MD		<b>ECHELON CIRCULAR™ Powered Stapler</b>   with Gripping Surface Technology   3D Stapling Technology   28mm Diameter Agrețoare a presiunii electrice   este tehnologie de suprafață agriștoare   Tehnologie de agrisare 3D   Diametru 28mm Powered Stapler   Endoscopic Surface Technology   3-D Stapling Technology   28mm Diameter Endoscópica lineal articulada Powered   Con tecnología Gripping Surface   Tecnología de sutura 3D   Diámetro 28mm Stapling device   with Gripping Surface Technology   3D stapling technology   28mm diameter Endoscópica circular   con tecnología de superficie de agarre   Tecnología de grietas 3D   Diámetro 28mm Agrețoare electrică   con tecnología de superficie de agarre   Tehnologie de grișuri 3D   Diametru de 28mm
1	GST60D CE MD		<b>ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads</b>   with Gripping Surface Technology   80mm Staple Line Length   3.8mm Open Staple Height   6 Rows   Gold Dispozitiv de încărcare endoscópica liniară articulată   este tehnologie de suprafață agriștoare   Lungimea liniei agrisă 80mm   Înălțimea de deschidere a agrisărilor 3,8mm   6 rânduri   Aur Reloads for endoscopic Linear Cutter   Endoscopic Surface Technology   80mm Staple Line Length   3.8mm Open Staple Height   6 Rows   Gold Recambio articuladora endoscópica lineal   con tecnología Gripping Surface   longitud de la línea de sutura 80mm   altura de apertura 3,8mm   6 filas   Oro Reloads for endoscopic Linear Cutter   Endoscopic Surface Technology   80mm Staple Line Length   3.8mm Open Staple Height   6 Rows   Gold Endoscópica lineal articuladora articulada   con tecnología de superficie agriștoare   longitud de la línea de grietas de 80mm   altura de apertura de 3,8mm   6 filas   Oro

  
LABELLDCOL176L761

Product Code

LCOL176

Lot Number

10241542

Procedure Pack Producer:  
 Johnson & Johnson Medical GmbH  
 Robert-Koch-Straße 1  
 D-22851 Nordenstedt, Germany

W0: 499989  
 2023-07-31    2021-05-25  
 (05) 367003603080  
 (17) 297791 1311041542

ETHICON

CD-108919712 / LCOL176-LAT-03

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**Attachment 3: Business Reply Form**

### Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and fax or email it to **[INSERT AFFILIATE NAME]** at **[INSERT FAX NUMBER]** or e-mail the form to **[INSERT AFFILIATE EMAIL ADDRESS]** **within 3 business days, even if you do not have product subject to this recall to return.**

If you have product subject to this recall to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

**[Account Name]**  
**[Account Address]**

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: <small>(number used to order J&amp;J product)</small>	Date:
Replacement Product Shipping Address (If different from above) or reference PO for replacement shipment:	
Signed*:	
<small>*Your signature provides confirmation that you have received and understood this notification</small>	
<i>Your comments are welcome.</i>	

**Product Inventory – please check one**

- We have NO inventory of product subject to this recall (removal).**
- We have product subject to this recall (removal) and are returning the following products:**

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	EXP DATE	GTIN / PRIMARY DI NUMBER	QUANTITY RETURNING (EACHES)
ECHELON FLEX™ Powered Plus Stapler	PSEE60A	U94V47	July 31, 2023	10705036014607	

PROCEDURE PACK CODE	PROCEDURE PACK LOT	QUANTITY RETURNING (EACHES)