

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

PROCEDURE PACK CODE	PROCEDURE PACK LOT	PROCEDURE PACK CODE	PROCEDURE PACK LOT	PROCEDURE PACK CODE	PROCEDURE PACK LOT
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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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)

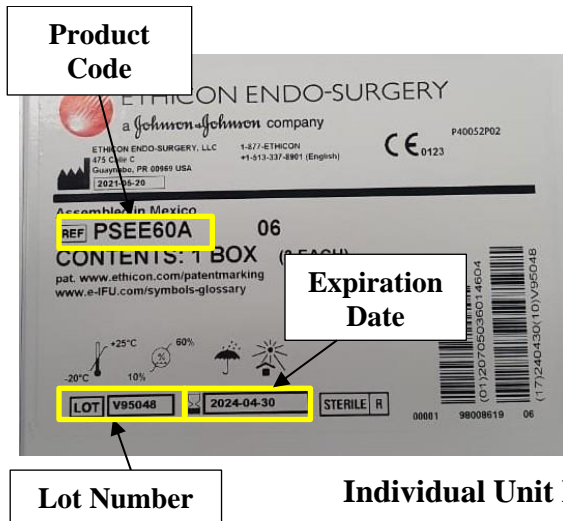
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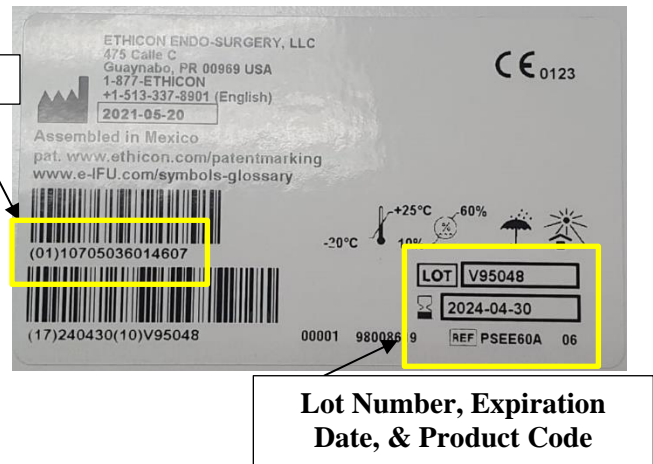
Attachment 1: Product Identification Tool

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.

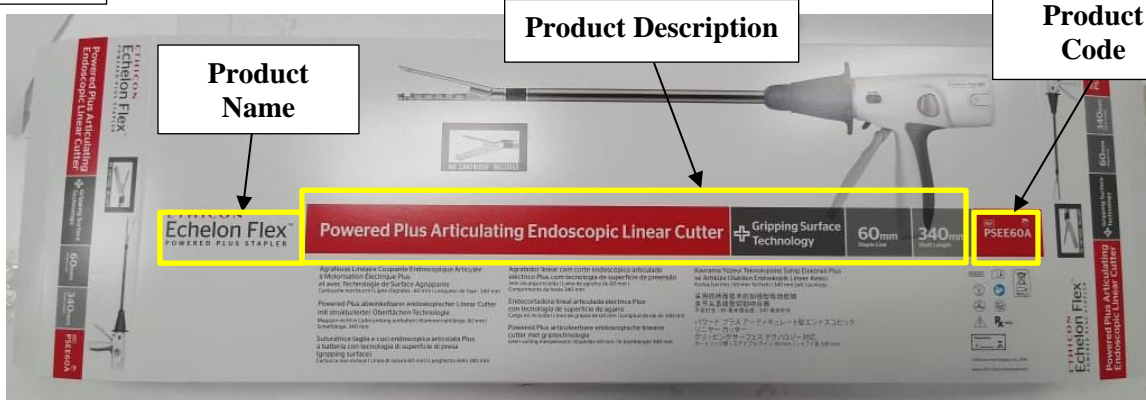
Sales Unit Box (Representative Sample)



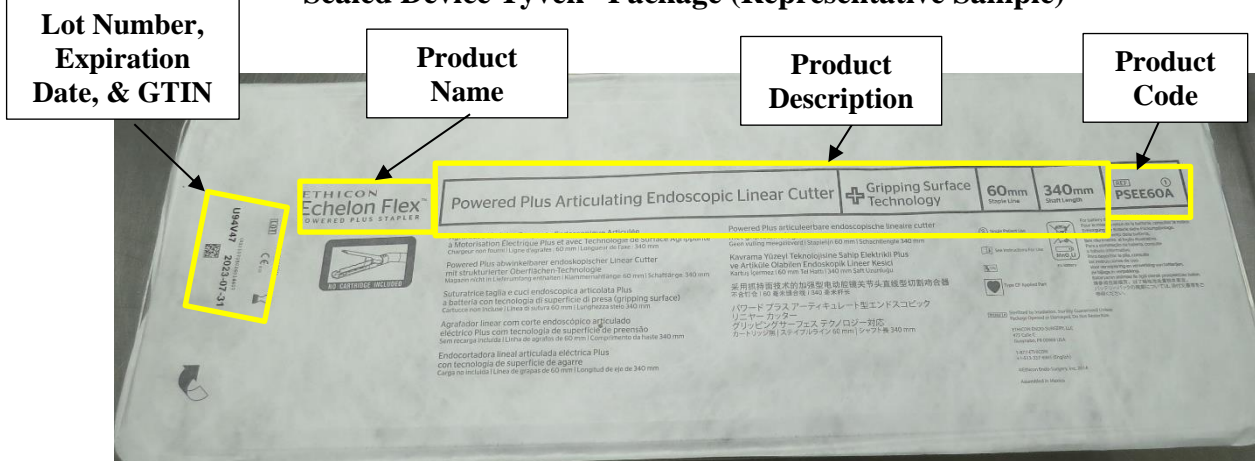
Individual Unit Box - Back (Representative Sample)



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

Lot Number

REF LCOL176 LAPAROSCOPIC COLON PACK

SET POUR COLON LAPAROSCOPIQUE
 BEHANDLINGSSET FÜR LAPAROSCOPISCHE COLON-OPERATION
 KIT PER LAPAROSCOPICAL COLON
 PAKKET VOOR LAPAROSCOPISCHE COLONPROCEEDURES

QTY	REF		
1	PSEE60A		ECHELON FLEX™ Powered Plus Articulating Endoscopic Linear Cutter with Gripping Surface Technology 80mm Staple Line 340mm Shaft Length Agreilles linéaires articulées endoscopiques articulées (ECHELON FLEX™ Plus à endoscopie linéaire) avec technologie de surface agrippante Longueur des lignes d'agrafe 80mm Longueur de la tige 340mm Powered Plus articulating endoscopic linear cutter Endoscopic Oberflächen-Technologie 80mm Klappmesser 340mm Schaftlänge Substanz endoskopische linear articuliert-Powered Plus Con-technologie Gripping Surface Lines d'agrafe 80mm Longueur de la tige 340mm Powered Plus articuliert endoskopische linear greift mit Gripping Surface Technology 80mm stapel 340mm schaftlänge Manipulatore endoscopice articulato endoscopice articulato con tecnologia di superficie aggrappante linee di aghi 80mm lunghezza dell'asta 340mm Confección lineal endoscópica articulada endoscópica con tecnología de superficie de agarre líneas de grapa 80mm Longitud del cuerpo 340mm Confecção lineal endoscópica articulada endoscópica con tecnologia de superfície de agarre linhas de grapa 80mm Comprimento do eixo de 340mm
1	CDH29P		ECHELON CIRCULAR™ Powered Stapler with Gripping Surface Technology 3D Stapling Technology 28mm Diameter Agrafeuse à incisionnel circulaire à avec technologie de surface agrippante Technologie d'agrafeuse 3D Diamètre 28mm Powered Stapler Endoskopische Oberflächen-Technologie 3-D-Klappmesser 28mm Durchmesser Substanz incisionnel-Powered Con-technologie Gripping Surface Technologie d'agrafeuse 3D Diamètre 28mm Agrafeuse articulée mit Gripping Surface Technology 3D stapling technology 28mm diameter Manipulatore circolari Powered con tecnologia di superficie aggrappante tecnologia di aghi 3D diametro 28mm Dispositivo endoscópico con tecnología de superficie de agarre tecnología de grapa 3D diámetro 28mm Agrafeuse endoscópica con tecnologia de superfície de agarre tecnologia de grapa 3D diâmetro de 28mm
1	GST60D		ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads with Gripping Surface Technology 80mm Staple Line Length 3.8mm Open Staple Height 6 Rows Gold Chargeur pour agrafeuse linéaire endoscopique articulée avec technologie de surface agrippante Longueur des lignes d'agrafe 80mm Hauteur des agrafes ouverte 3.8mm 6 rangées Or Magazine für endoskopischer linear cutter mit endoskopischer Oberfläche 80mm Klappmesserlänge 3.8mm offene Klappmesserhöhe 6 Reihen Gold Recambio endoscópico lineal articulado con tecnología Gripping Surface longitud de la línea de sutura 80mm altura de grapa abierta 3.8mm 6 file Oro Neuzetel voor endoscopische linear greift met Gripping Surface Technology 80mm stapelhoogte 3.8mm open stapel 6 rijen Goud Ammunition, recambio endoscópico articulado con tecnología de superficie aggrappante linee di aghi 80mm altezza di grapa aperta 3.8mm 6 righe Oro Charge de cartouche linéaire endoscopique con tecnologia de superficie de agarre longitud de línea de grapa 80mm altura de grapa abierta 3.8mm 6 file Oro Recargas para cartucho linear endoscópico con tecnologia de superfície de agarre comprimento da linha de grapa de 80mm altura de grapa aberta de 3.8mm 6 file Ouro

Product Code

Lot Number

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

ETHICON

CD-108810712 / 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: (number used to order J&J product)	Date:
Replacement Product Shipping Address (If different from above) or reference PO for replacement shipment:	
Signed*:	
<i>*Your signature provides confirmation that you have received and understood this notification</i>	
<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)