ETHICON
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

# 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.

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 | | |

# URGENT: FIELD SAFETY NOTICE

**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.

# URGENT: FIELD SAFETY NOTICE

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

– Voluntary Product Recall (Removal) –

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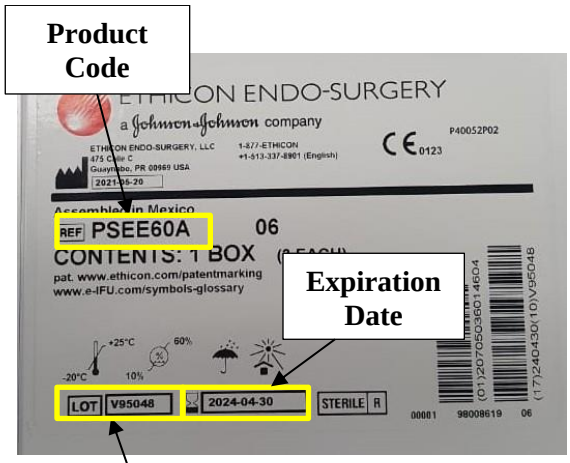
**ECHELON FLEX™ Powered Plus Stapler:** Product Code PSEE60A, Lot U94V47

– Voluntary Product Recall (Removal) –

**Attachment 1:** Product Identification Tool

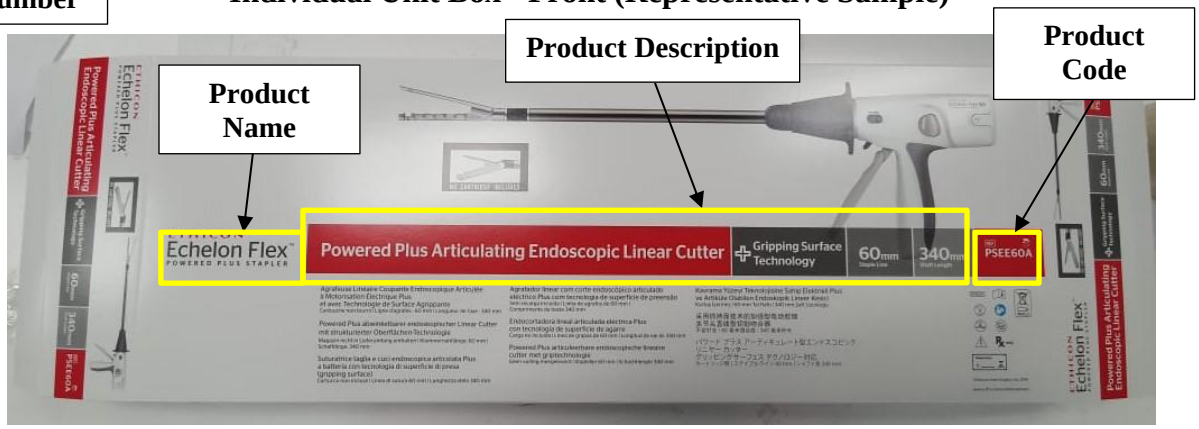
This tool will help customers identify the location of the product name, product code, GTIN, lot number, and expiration date of ECHELON FLEX™ Powered Plus Stapler, subject to this recall by using the packaging labels. This document applies to Product Code PSEE60A, Lot U94V47.

**Sales Unit Box (Representative Sample)**

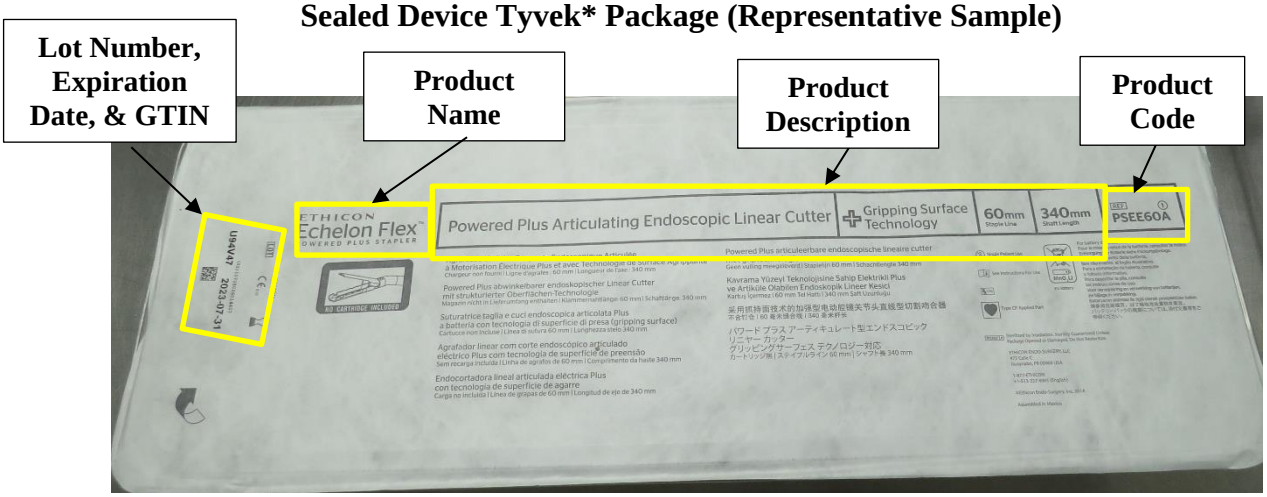



**Individual Unit Box - Back (Representative Sample)**


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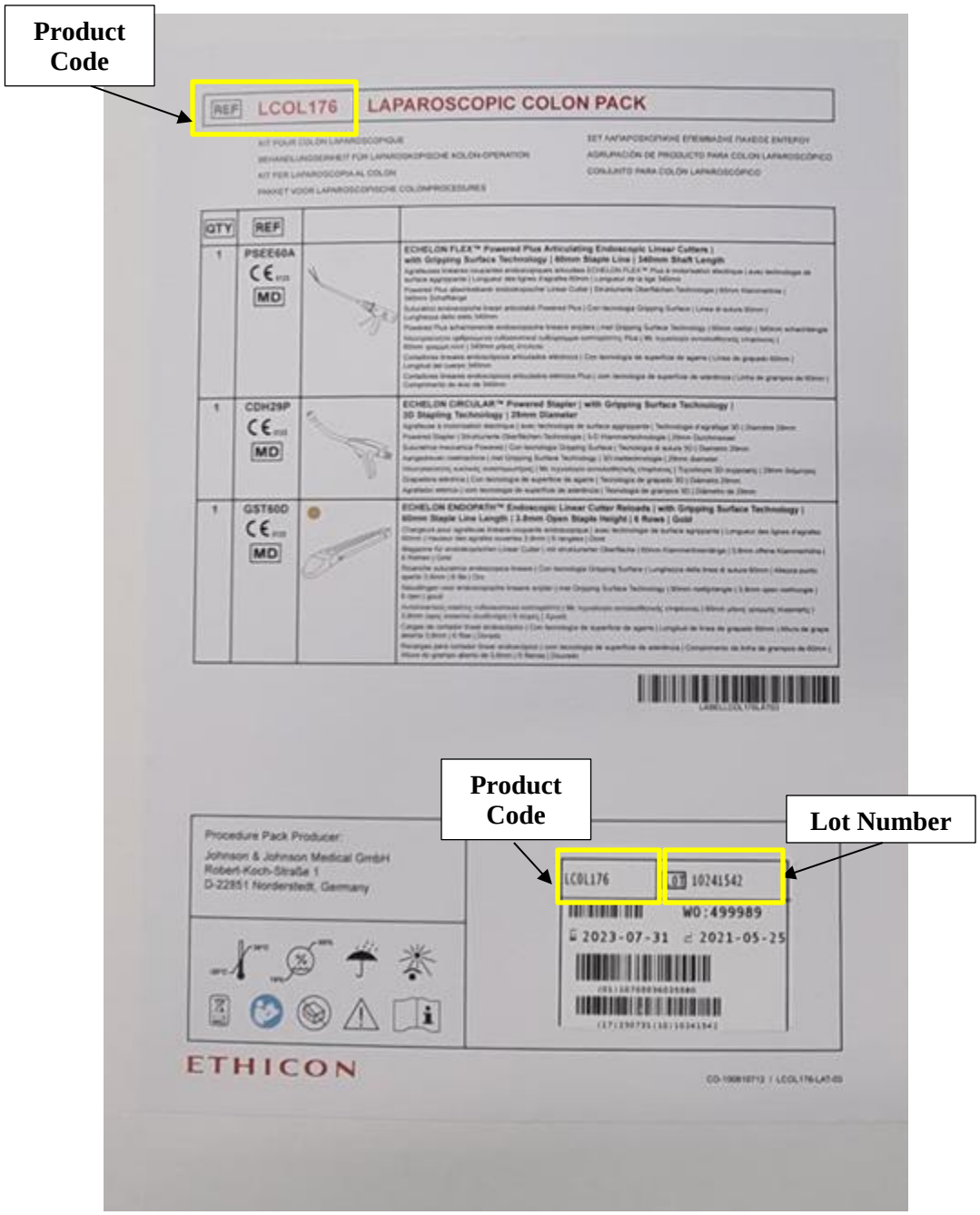
**ECHELON FLEX™ Powered Plus Stapler:** Product Code PSEE60A, Lot U94V47

– Voluntary Product Recall (Removal) –

**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)**



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

– Voluntary Product Recall (Removal) –

**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:<br>(number used to order J&J product) | Date: |
| Replacement Product Shipping Address (If different from above) or reference PO for replacement shipment: | |
| Signed*:<br><br>**Your signature provides confirmation that you have received and understood this notification* | |
| *Your comments are welcome.* | |

**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) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |