

Ethicon Recalls ECHELON FLEX™ ENDOPATH® Staplers for Failure to Completely Form Staples

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- ECHELON FLEX™ ENDOPATH® Staplers:
 - ECHELON Flex 60 Endopath Stapler, Articulating Endoscopic Linear Cutter (EC60A)
 - ECHELON Flex 60 Powered Plus Compact Articulating Endoscopic Linear Cutter (PCEE60A)
 - ECHELON Flex 60 Powered Plus Articulating Endoscopic Linear Cutter, 44cm Shaft Length (PLEE60A)
 - ECHELON Flex 60 Powered Plus Articulating Endoscopic Linear Cutter, 34cm Shaft Length (PSEE60A)
- Product Codes: EC60A, PCEE60A, PLEE60A, PSEE60A
- Lot Numbers: See specific lot numbers in the table below
- Manufacturing Dates: July 18, 2019 – August 3, 2019
- Distribution Dates: August 1, 2019 – September 26, 2019
- Devices Recalled in the U.S.: 8,256
- Date Initiated by Firm: October 3, 2019

Device Use

The Echelon Flex Endopath staplers are sterile, single patient use devices that cut and staple internal tissue. The staplers can be used in open or in minimally-invasive surgical procedures, including gynecologic, urologic, thoracic, pediatric, and general surgeries.



Reason for Recall

Ethicon is recalling these devices because some devices may contain an out of specification component within the jaw of the device, which could lead to malformed staples. If a problem with the staple line is not recognized or is not adequately addressed, there is a potential risk of prolonged surgery, postoperative connection (anastomotic) leak, hemorrhage, hemorrhagic shock, additional surgical intervention, or death. As of October 3, 2019, 7 serious injuries and 1 death had been reported to Ethicon for affected product codes.

Who May be Affected

- Patients who have had or may undergo surgery involving staplers for internal use
- Surgeons who have performed or will perform surgeries using staplers for internal use

What to Do

On October 3, 2019, Ethicon sent a letter to customers who purchased the affected staplers and provided instructions. Health care facilities, distributors, and other customers must:

1. Examine their inventory immediately to determine if they have product subject to this recall on hand and quarantine such product(s).
2. Remove the product subject to this voluntary recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in their facility who needs to be informed.
3. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
4. Have completed the Business Reply Form (BRF) confirming receipt within 3 business days of receipt of the firm's letter, **even if they do not have product subject to this**

recall.

5. Keep the letter visibly posted for awareness until all product subject to this recall has been returned to Stericycle. While processing their returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.
6. If customers have the affected product, they 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 subject to this recall, photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the recall notification letter. Ethicon will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by calling Stericycle at 1-866-918-8756.

In addition, the FDA's letter to health care providers on surgical staplers and staples (/medical-devices/letters-health-care-providers/safe-use-surgical-staplers-and-staples-letter-health-care-providers) from March 2019 includes general recommendations for surgeons.

Contact Information

If you require any assistance with returning product, please contact Stericycle at 1-866-918-8756 and reference Event #7148.

If you have additional questions regarding this recall or to report any customer complaints, please contact Ethicon Customer Support Center at 1-877-ETHICON (1-877-384-4266). The Customer Support Center is open Monday through Friday, 8:00 AM to 6:00 PM ET.

Full List of Affected Devices

PRODUCT CODE	PRODUCT LOT				DESCRIPTION
EC60A	T9408M	T94A9Z			ECHELON FLEX™ ENDOPATH® 60mm Stapler – 340mm shaft
PCEE60A	T93Z9Y	T9411A			ECHELON FLEX™ Powered Plus ENDOPATH® 60mm Stapler – 280mm shaft
PLEE60A	T93X95	T93Z75	T93Z2W	T9413Z	ECHELON FLEX™ Powered Plus ENDOPATH® 60mm Stapler – 440mm shaft
	T93Z1G	T93Y4M	T94045		
	T94117	T93X17	T94087		
	T93Z2X	T9405L	T94253		
PSEE60A	T93Z5W	T93Z5X	T9405V	T9405W	ECHELON FLEX™ Powered Plus ENDOPATH® 60mm Stapler – 340mm shaft

PRODUCT CODE	PRODUCT LOT			DESCRIPTION
	T93Z3F	T9401L	T93Y8X	
	T94008	T9400D	T93Z5R	

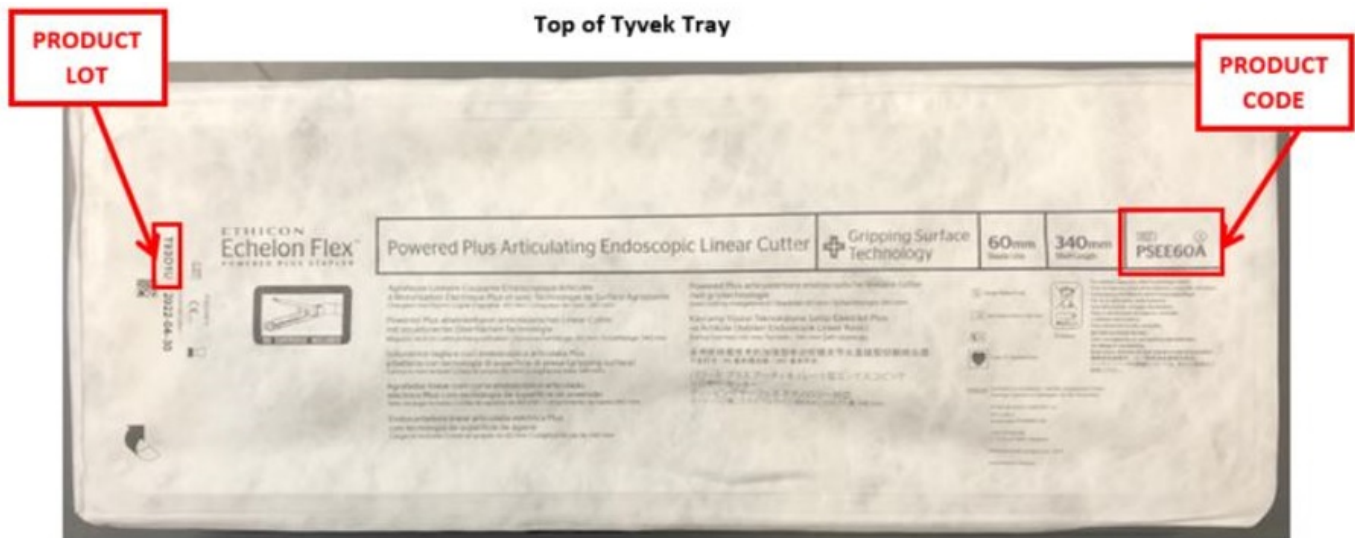
Single Unit Carton (Containing (1) Sealed Tyvek Tray)



Label on Single Unit Carton



Tyvek Tray (Containing (1) Echelon Flex Endopath 60mm Stapler)



How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.

Additional Resources

- Recall database (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm>)
- Safe Use of Surgical Staplers and Staples - FDA Letter to Health Care Providers (March 8, 2019) (</medical-devices/letters-health-care-providers/safe-use-surgical-staplers-and-staples-letter-health-care-providers>)
- Surgical Staplers and Staples Webpage (</medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples>)