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Ethicon Recalls Circular Staplers for Insufficient Firing and 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

- Recalled Product(s):
 - Endo-Surgery Curved Intraluminal Stapler with Adjustable Height Staples and
 - Endo-Surgery Endoscopic Curved Intraluminal Stapler with Adjustable Height Staples
- Product Codes: CDH21A, CDH25A, CDH29A, CDH33A, ECS21A, ECS25A, ECS29A, ECS33A (*Product codes are located on the front of the single unit carton.*)
- Manufacturing Dates: March 6, 2018 to March 6, 2019
- Distribution Dates: March 15, 2018 to March 8, 2019
- Devices Recalled in the U.S.: 92,496

Device Use

Surgeons use Ethicon Endo-Surgery Intraluminal Staplers in the gastrointestinal tract for creating connections between structures (anastomoses) in surgical procedures



Reason for Recall

Through investigation of complaints and returned products, Ethicon confirmed uncut washers in the stapler and malformed staples occur with their intraluminal circular staplers due to insufficient firing, which can compromise staple line integrity. When the washer is cut, confirming completion of the firing cycle, the surgeon experiences an audible and tactile crunch. Failure to cut the washer suggests complete 360-degree staple line failure.

In addition, an investigation of the manufacturing process detected a shift in a process, which occurred in March 2018 and continued through March 8, 2019, at which time the line was shut down.

The use of affected product may cause serious patient harm or death. Ethicon confirmed serious injuries to two patients. Misfiring of the stapler resulted in an additional resection -- of the middle rectum in one patient and the lower rectum in another patient -- during the planned resection of the upper rectum. Potential risks to patients include death, sepsis, bleeding, the need for permanent ostomy "bag," life-long nutritional and digestive issues, leak in the closure (anastomotic leak), additional surgeries, need for additional closures (anastomoses), need for antibiotics, and the need for additional imaging studies.

Who May be Affected

- Surgeons who have performed gastrointestinal surgeries
- Patients who have had or may undergo gastrointestinal surgery, such as patients with colorectal cancer and bariatric patients

What to Do

The FDA's recent 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) includes general recommendations for surgeons.

Surgeons who typically use these staplers have other options, including using:

- Manual staplers from other manufacturers,
- Powered staplers from Ethicon or other manufacturers,

Additionally, surgeons who typically use these staplers may consider performing an alternative approach to the surgery, such as:

- Open surgery with an alternative of handsewn closure (anastomosis)
- Delayed surgery
- Minimally invasive surgery

On April 11, 2019, Ethicon notified customers who purchased the affected staplers (consignees) and provided instructions. Health care facilities, distributors, and other customers should:

- Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s).
- Remove the product subject to this recall and, for health care facilities, communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.
- Return unused impacted Intraluminal Stapler (ILS) subject to this recall that are in their inventory immediately. To receive replacement product, customers must return product subject to this recall by June 30, 2019. Any non-affected product and any product returned after the date specified will not be replaced.
- For health care facilities, if you forwarded any product subject to this recall to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.

- Distributors do not need to contact end customers regarding this action. Ethicon will directly communicate with customers about this recall.

Contact Information

If you require any assistance with returning product, please contact Stericycle at 1-888-671-8832 and reference Event # 5011.

If you have additional questions regarding this recall, please contact Ethicon Customer Support Center at 1-877-ETHICON (1-877-384-4266) Monday through Friday, 7:30 a.m. to 6:30 p.m. Eastern.

Date Recall Initiated

04/11/2019

Additional Resources

- Safe Use of Surgical Staplers and Staples - FDA Letter to Health Care Providers (May 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)

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.