ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT: MEDICAL DEVICE FIELD ACTION (Corrective Action)

Intraluminal Staplers (ILS)

Product Codes: ECS21A, ECS25A, ECS29A, ECS33A, SDH21A, SDH25A, SDH29A, SDH33A, CDH21A, CDH25A, CDH29A, CDH33A

March 30, 2019

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

At Ethicon Endo-Surgery, LLC. ("Ethicon"), our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

We have initiated a medical device Field Action (corrective action) of 701 (WW) lots of Intraluminal Staplers (ILS). Through investigation of complaints and returned products, we have confirmed occurrence of uncut washers and malformed staples with our ILS circular staplers, which can compromise staple line integrity. If a problem with the staple line is not adequately addressed or is not recognized, there is a potential risk of postoperative anastomotic leak, gastrointestinal injury, hemorrhage, or hemorrhagic shock.

Ethicon has received reports of Adverse Events related to this field action (notification).

Based on Ethicon's analysis of complaints received to date and estimated device usage, the predicted occurrence of complaints for malformed staples has increased but is expected to remain below 0.1%. Ethicon is implementing corrective actions to resolve the shift in product performance.

Customer Action:

If you have alternative product available, please return all product subject to this notification (Reference Table 1 for product listing). Ethicon recognizes due to worldwide supply issues with Intraluminal Staplers (ILS), alternative product may not be available. If alternative products to complete required surgeries are not available, it is critical to adhere to the following information.

- The firing stroke must be completed. Do not partially fire the instrument. Incomplete firing can result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device.
- Ensure that the tissue thickness is within the indicated range, and that it is evenly distributed within the instrument. Excess tissue on one side may result in unacceptable staple formation and can result in staple line leakage.
- Ensure that the firing trigger is fully squeezed to ensure proper staple formation and cutting of tissue.
- The surgeon should notice both tactile and audible feedback during the firing sequence when cutting through the breakaway washer.
- Ensure that donuts and cutting washer transections are both complete. If donuts or cutting washer transection are not complete, the anastomosis should be carefully checked for leakage and appropriate repairs made.

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- Always inspect the anastomotic staple line for hemostasis and check the completed anastomosis for integrity and leakage. Metal clips, staples, or sutures contained in the area to be stapled may affect the integrity of the anastomosis. Corrective action, if required, may include the use of sutures or electrocautery.
    - In addition:
        - If an intra-operative leak is observed, remediation should be dictated by your clinical judgement.
        - A negative peri-operative leak test does not guarantee the absence of a leak during the post-operative course; normal clinical surveillance remains essential.

The scope of this Field Action includes ALL Intraluminal Staplers (ILS) from the product codes and expiration dates listed in the table below.

Table 1 – Product Subject to this Field Action

PRODUCT NAME	PRODUCT CODE	All Lots within EXPIRATION Date Range	DESCRIPTION/SIZE
Curved Intraluminal Stapler (ILS)	CDH21A	December 2022 – March 2024	21mm Curved Intraluminal Stapler
Curved Intraluminal Stapler (ILS)	CDH25A	December 2022 – March 2024	25mm Curved Intraluminal Stapler
Curved Intraluminal Stapler (ILS)	CDH29A	December 2022 – March 2024	29mm Curved Intraluminal Stapler
Curved Intraluminal Stapler (ILS)	CDH33A	December 2022 – March 2024	33mm Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS21A	February 2023 – March 2024	21mm Endoscopic Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS25A	February 2023 – March 2024	25mm Endoscopic Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS29A	February 2023 – March 2024	29mm Endoscopic Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS33A	February 2023 – March 2024	33mm Endoscopic Curved Intraluminal Stapler

Product subject to this Field Action in your inventory can be identified by using the Product Identification Tool (Attachment 1).

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Intraluminal Stapler (ILS)

Product Codes: ECS21A, ECS25A, ECS29A, ECS33A, SDH21A, SDH25A, SDH29A, SDH33A, CDH21A, CDH25A, CDH29A, CDH33A

ACTION REQUIRED:

1. Ethicon is requesting that you examine your inventory to determine if you may have impacted product. Refer to **Attachment 1** for the Product Identification Tool to identify the products that are subject to this Field Action (notification) by using package labels.

2. If you have alternative product available, please return all products subject to this notification (Reference Table 1 for products listing). Ethicon recognizes due to worldwide supply issues with Intraluminal Staplers (ILS), alternative product may not be available. If alternative products to complete required surgeries are not available and in view of the increased risk of malformed staples and possibly associated anastomotic failure, it is critical to adhere to the instructions provided above.

3. If any product subject to this action has been forwarded to another facility, contact that facility to make them aware of the notification.

4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and send to [saldawal@its.jnj.com]. within three (3) business days. **Please return the BRF even if you do not have the product lots subject to this notification.**

5. If you are returning impacted product in your inventory, please contact us at [saldawal@its.jnj.com] for replacement/credit and next action to be taken with impacted products .

ATTACHMENTS:
Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form (BRF)

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ATTACHMENT 1: Product Identification Tool for Intraluminal Staplers (ILS)

This tool will help customers identify product codes and expiration dates of Intraluminal Staplers (ILS) subject to this notification by using the packaging labels. Please refer to table above for a list of all product codes with expiration dates subject to this notification.

SINGLE UNIT CARTON (CONTAINING (1) SEALED TYVEK TRAY)

FRONT OF SINGLE UNIT CARTON

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ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and send this form to [Suzan Al Dawalibi: saldawal@its.jnj.com] **within 3 business days, even if you do not have product subject to this field action to return.**

Please complete the following information: - add check box (Distributor)

☐ We hereby acknowledge receipt of this medical device field action letter from Ethicon regarding Intraluminal Staplers (ILS). We have distributed this information to all staff within our facility that use the impacted products and will maintain a copy of this notice with the identified product(s).

Product Receipts – please check one (Hospital/Customer):

☐ We have NO impacted Intraluminal Staplers (ILS) subject to this field action (notification), however we will maintain a copy of this notice within our facility.

☐ We have impacted Intraluminal Staplers (ILS) subject to this field action (notification), however we do not have an acceptable alternative product and we chose to continue to use the product. We will maintain a copy of this notice within our facility.

☐ We are returning impacted Intraluminal Staplers (ILS) and below are the quantities noted.

PRODUCT NAME	Circle PRODUCT CODE	EXPIRATION Date	Quantity Returning (Eaches) and Lot number
Curved Intraluminal Stapler (ILS)	CDH21A CDH25A CDH29A CDH33A		/
Endoscopic Curved Intraluminal Stapler (ILS)	ECS21A ECS25A ECS29A ECS33A		/

Account Name: _____

Account Address: _____

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Signed*: Comments if any: **Your signature provides confirmation that you have received and understood this notification*	

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