

**IMPORTANT MESSAGE  
TO WHOM IT MAY CONCERN**

Date April 4th 2019  
Page 1/4

**URGENT FIELD SAFETY NOTICE**

**Intraluminal Staplers (ILS)**

**Product codes: ECS21A, ECS25A, ECS29A, ECS33A, CDH21A,  
CDH25A, CDH29A, CDH33A (specific lots)**

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 Safety Corrective Action of 360 lots of Intraluminal Staplers (ILS) distributed in EMEA. 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 Safety Corrective Action.**

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 and 2 for product listing).

Ethicon recognizes due to worldwide supply issues with Intraluminal Staplers (ILS), alternative product may not be available.

Datum April 4th 2019  
Seite 2/4

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.
- 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 Safety Corrective Action** includes **ALL Intraluminal Staplers (ILS)** from the product codes listed in the attached documents “**Table 1 - Products Subject to this Field Safety Corrective Action**” and “**Table 2 - Kits Subject to this Field Safety Corrective Action**”.

Datum April 4th 2019  
Seite 3/4

## **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 Safety Corrective Action by using package labels.
2. If you have alternative product available, please return all products subject to this notification (reference Table 1 and 2 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 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 via e-mail or fax to: [ssurmon1@its.jnj.com](mailto:ssurmon1@its.jnj.com) or 058 231 25 24 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 have acceptable alternative devices and decide to return unused impacted Intraluminal Staplers subject to this Field Safety Corrective Action that are in your inventory, please return them by June 30, 2019 to the address mentioned under point 6, to receive replacement product/credit. Any non-affected product and any product returned after the date specified will not be replaced.
6. To return product subject to this action, photocopy the completed BRF, place it in the box with the products and send it to the following address:

**Johnson & Johnson AG**  
**c/o Postlogistik**  
**Keyword «ILS»**  
**Allmendstrasse 8**  
**5612 Villmergen**

We recognize the Field Safety Corrective Action of the Intraluminal Staplers Products may be disruptive to your facility and we apologize for any inconvenience this may cause.

Datum April 4th 2019  
Seite 4/4

If you have additional questions regarding this Field Safety Corrective Action or to report any customer complaints, please contact your Product Specialist.

Kind regards,

Valentine Loertscher  
Business Unit Lead One Ethicon

Victor Alund  
Business Quality Lead Switzerland

*This letter is done automatically and is valid without signature.*

**Attachments**

Table 1 – Products subject to this Field Safety Corrective Action

Table 2 – Kits subject to this Field Safety Corrective Action

Attachment 1 – Product Identification Tool

Attachment 2 – Business Reply Form

**TABLE 1**

**Products subject to this Field Safety Corrective Action**

Produktbeschreibung	Artikel-Nr.	Lot-Nr.			
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (21mm)	CDH21A	R40E9V	R40H10	R40L7V	R5AD4T
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (25mm)	CDH25A	R4073T	R4074U	R40A0Z	R40F4J
		R40F5T	R40H3T	R40M0T	R40N79
		R40R5H	R40T7H	R40V9A	R40X3N
		R40Z50	R57549	T5A18K	

Produktbeschreibung	Artikel-Nr.	Lot-Nr.			
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (29mm)	CDH29A	R4074A	R40H8M	R40Y7F	R4193C
		R4078D	R40H92	R40Z0L	R41947
		R4078E	R40J9D	R40Z0X	R41962
		R4080X	R40J9J	R40Z4X	R5AE8R
		R40819	R40K51	R40Z7T	R5AM2J
		R4081K	R40K7K	R40Z7V	R5AW3N
		R4081R	R40K82	R4106V	R5C435
		R40833	R40K83	R41073	R5C505
		R4083F	R40L4V	R41133	T40014
		R4096J	R40L57	R41150	T4007R
		R4096Y	R40L9A	R4115X	T40189
		R40A1F	R40L9J	R41164	T4019U
		R40A59	R40M07	R41194	T4028N
		R40A8U	R40M13	R41205	T5A311
		R40C18	R40M22	R41224	T5A48U
		R40C93	R40N86	R4125N	
		R40D0T	R40N8N	R41336	
		R40D0V	R40P23	R4133U	
		R40D62	R40P24	R41385	
		R40D6K	R40P84	R4138L	
		R40D6T	R40R0H	R41444	
		R40D71	R40R30	R41448	
		R40D7D	R40R3E	R4145H	
		R40D8F	R40R6N	R4152Z	
		R40D95	R40R80	R41538	
		R40D9N	R40T0C	R4153Y	
		R40E2V	R40T1L	R41564	
		R40E3Z	R40T84	R41565	
		R40E48	R40U1H	R4170F	
		R40E5Y	R40U4F	R4172U	
		R40F7Z	R40U4L	R4175Y	
		R40G32	R40V0C	R41762	
		R40G79	R40V94	R4177Y	
		R40G8A	R40V9U	R4177Z	
		R40G91	R40W0Z	R4186N	
		R40G97	R40W1A	R4186W	
		R40G9N	R40W28	R4190F	
		R40H01	R40X1J	R4190R	
		R40H6W	R40X5F	R4190T	
		R40H8C	R40X7M	R41917	

Produktbeschreibung	Artikel-Nr.	Lot-Nr.			
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (33mm)	CDH33A	R4075V	R40K31	R4112V	
		R4075X	R40L8Z	R41189	
		R40781	R40N54	R4137D	
		R40974	R40N8G	R41579	
		R40A5L	R40P9C	R4170T	
		R40A9W	R40R3F	R41756	
		R40D9T	R40U2P	R5759V	
		R40E86	R40U2W	R5AD34	
		R40F61	R40W1E	T4028H	
		R40G3P	R40X1X		
		R40G4X	R40X70		
		R40J0A	R40Z81		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (21mm)	ECS21A	R93480	R94G5T		
		R93V70	R94V8P		
		R9463Z	R95335		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (25mm)	ECS25A	R92T17	R9474D	R9589U	
		R92X8A	R94G76	T9234N	
		R9323R	R94K3K		
		R93483	R94P6G		
		R93C6D	R94Z5W		
		R93M5L	R9503N		
R93Y34	R9569P				
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (29mm)	ECS29A	R92R99	R93K4N	R94T0Z	
		R92T1A	R93K4P	R94W19	
		R92T41	R93L86	R94W7D	
		R92U1T	R93T9M	R94Y07	
		R92U4H	R93V2T	R94Z20	
		R92U4N	R93X7D	R94Z87	
		R92W3F	R93X9T	R95157	
		R92X9L	R93Z1M	R9524L	
		R92Y3M	R94071	R95514	
		R9312M	R9477U	R95515	
		R93151	R9493W	R9571Z	
		R9354N	R9495L	R95902	
		R9385H	R94D21	T9224W	
		R9398G	R94D8W	T9224X	
		R93C7N	R94G8L	T9228Z	
		R93D2X	R94J4H	T9249D	
R93H38	R94K1R	T9251M			
R93J36	R94P6F	T9280E			
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (33mm)	ECS33A	R92T1C	R9401Y	R95720	
		R93895	R9468A		
		R93K9L	R94N5P		

**TABLE 2**

**Kits subject to this Field Safety Corrective Action**

Kit Art-Nr.	Kit Lot-Nr.	Kit Art-Nr.	Kit Lot-Nr.	Kit Art-Nr.	Kit Lot-Nr.	Kit Art-Nr.	Kit Lot-Nr.
LCOL124	10087601	LCOL124	10098274	LCOL124	10106981	LCOL124	10115777
LCOL124	10087615	LCOL124	10098285	LCOL124	10106990	LCOL124	10117851
LCOL124	10087621	LCOL124	10098289	LCOL124	10107002	LCOL124	10117868
LCOL124	10087629	LCOL124	10098292	LCOL124	10107005	LCOL124	10117875
LCOL124	10087635	LCOL124	10098375	LCOL124	10107011	LCOL124	10117879
LCOL124	10095680	LCOL124	10101622	LCOL124	10112176	LCOL124	10121492
LCOL124	10095685	LCOL124	10101625	LCOL124	10112188	LCOL124	10121500
LCOL124	10095700	LCOL124	10101629	LCOL124	10112199	LCOL124	10121501
LCOL124	10095702	LCOL124	10101643	LCOL124	10112207	LCOL124	10121508
LCOL124	10095704	LCOL124	10101649	LCOL124	10112227	LCOL124	10121511
LCOL124	10095706	LCOL124	10101653	LCOL124	10112241	LCOL124	10121521
LCOL124	10095709	LCOL124	10101659	LCOL124	10112355	LCOL124	10121524
LCOL124	10095714	LCOL124	10101667	LCOL124	10112365	LCOL124	10121533
LCOL124	10098229	LCOL124	10106963	LCOL124	10115762		
LCOL124	10098235	LCOL124	10106971	LCOL124	10115765		
LCOL124	10098263	LCOL124	10106980	LCOL124	10115771		
LCOL126	10110497	LCOL126	10110510	LCOL126	10119854	LCOL126	10119879
LCOL126	10110501	LCOL126	10110523	LCOL126	10119861	LCOL126	10119890
LCOL135	10095106	LCOL135	10095111	LCOL135	10095116		
LCOL135	10095108	LCOL135	10095113	LCOL135	10095121		
LCOL89	10098997	LCOL89	10101185	LCOL89	10106819	LCOL89	10107023
LCOL89	10099000	LCOL89	10101203	LCOL89	10106828	LCOL89	10107028
LCOL89	10099002	LCOL89	10101210	LCOL89	10106862	LCOL89	10107032
LCOL89	10101180	LCOL89	10106817	LCOL89	10107013		



## Attachment 1

### Product Identification Tool for Intraluminal Stapler (ILS)

This tool will help customers identify product and lot codes 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 lot numbers subject to this notification.

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

#### FRONT OF SINGLE UNIT CARTON



## Attachment 2

### BUSINESS REPLY FORM

#### **URGENT FIELD SAFETY NOTICE**

Intraluminal Staplers (ILS)

Product codes: ECS21A, ECS25A, ECS29A, ECS33A, CDH21A,  
CDH25A, CDH29A, CDH33A (specific lots)

**Please complete the following information: - add check box:**

- We hereby acknowledge receipt of this Field Safety Notice 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:**

- We have NO impacted Intraluminal Staplers (ILS) subject to this Field Safety Corrective Action, however we will maintain a copy of this notice within our facility.
- We have impacted Intraluminal Staplers (ILS) subject to this Field Safety Corrective Action, 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	Coe	Lot Number	Quantity returning (eaches)
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (21mm)	CDH21A		
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (25mm)	CDH25A		
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (29mm)	CDH29A		
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (33mm)	CDH33A		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (21mm)	ECS21A		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (25mm)	ECS25A		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (29mm)	ECS29A		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (33mm)	ECS33A		

Kit Code	Kit Lot Number	Quantity returning (eaches)

**Hospital and location:** \_\_\_\_\_

Print Name of Person Completing Business Reply Form	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Signed*:	
<i>Your comments are welcome:</i>	

*\*Your signature provides confirmation that you have received and understood this notification.*