

URGENT: FIELD SAFETY NOTICE

Intraluminal Staplers (ILS)

Product Codes: ECS21A, ECS25A, ECS29A, ECS33A,
CDH21A, CDH25A, CDH29A, CDH33A (specific lots) – Voluntary Product Recall

June 27, 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.

On [3-Apr-2019] our records indicate we notified you of a medical device Field Safety Corrective Action for specific lots of Ethicon’s Intraluminal Staplers (ILS) distributed in EMEA. In March 2019, Ethicon initiated a medical device Field Safety Corrective Action due to the potential occurrence of uncut washers and malformed staples with our Intraluminal Staplers (ILS). Ethicon recognized that due to worldwide supply issues with Circular Stapler, alternative product may not have been available at that time. If alternative product was available, you were advised to return all product subject to the Field Safety Notice.

At this time, Ethicon has identified the root cause and implemented corrective actions to resolve the issue. Distribution of Ethicon’s Intraluminal Stapler (ILS) devices resumed starting in June 2019 in a phased approach, and as a result we have decided to recall any remaining product from the impacted lots. When product supply at your hospital or facility has been reestablished of Intraluminal Stapler (ILS) devices, please return all inventory of product subject to this removal.

Note: We understand that you may have already returned all impacted products from your inventory and that this letter may be redundant and disruptive for you. However, at the same time we need to ensure that all impacted devices will be returned as alternatives will now become available.

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

Table 1 – Product Subject to this Field Safety Corrective Action

Product Name	Product Code	Lot#			
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (21mm)	CDH21A	R40718	R40K1D	R40U9V	R41199
		R40C0X	R40L7V	R40X1T	R5762R
		R40E9V	R40M38	R40Z4V	R5AD4T
		R40H10			
Ethicon Endo-Surgery Curved Intraluminal Staplers	CDH25A	R40702	R40G3A	R40R67	R57549
		R4073T	R40H19	R40T7H	R5754A

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Product Name	Product Code	Lot#			
(ILS) (25mm)		R4074U	R40H3T	R40U2R	R5AC9G
		R4086M	R40M0T	R40V9A	R5AT4W
		R40A0Z	R40M5E	R40W8Y	R5AX2D
		R40A51	R40N5E	R40X3N	R5C32J
		R40D2G	R40N79	R40Z50	T5A18K
		R40F3C	R40P80	R41083	T5A53R
		R40F4J	R40R5H	R4108M	T5A79M
		R40F5T			
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (29mm)	CDH29A	R4074A	R40G91	R40T1V	R41444
		R4078D	R40G97	R40T48	R41448
		R4078E	R40G9N	R40T84	R4145D
		R4080X	R40H01	R40T9H	R4145H
		R40813	R40H08	R40U1H	R4152Z
		R40819	R40H6W	R40U1N	R41538
		R4081K	R40H8C	R40U4F	R4153Y
		R4081R	R40H8M	R40U4L	R41564
		R40833	R40H92	R40V0C	R41565
		R4083F	R40H9E	R40V94	R41703
		R40863	R40J9D	R40V9U	R4170F
		R4096J	R40J9J	R40W0Z	R4172U
		R4096Y	R40K51	R40W1A	R4175Y
		R40A1F	R40K7K	R40W28	R41762
		R40A59	R40K7T	R40X1J	R4177Y
		R40A8U	R40K82	R40X5F	R4177Z
		R40C18	R40K83	R40X7M	R4186N
		R40C93	R40L4V	R40Y7F	R4186W
		R40D0T	R40L57	R40Z0L	R4190F
		R40D0V	R40L9A	R40Z0X	R4190R
		R40D62	R40L9J	R40Z4X	R4190T
		R40D6K	R40M07	R40Z7T	R41917
		R40D6T	R40M13	R40Z7V	R4193C
		R40D71	R40M22	R4106V	R41947
		R40D7D	R40M2A	R41073	R41962
		R40D8F	R40M5U	R41133	R5756Z
		R40D95	R40N86	R41134	R5AE8R
		R40D9N	R40N8N	R41150	R5AM2J
		R40E2A	R40N8P	R4115X	R5AW3N
		R40E2V	R40P23	R41164	R5C435
		R40E2W	R40P24	R41194	R5C505
		R40E3Z	R40P84	R41205	T40014
		R40E48	R40R0H	R4121N	T4007R

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Product Name	Product Code	Lot#			
		R40E5Y	R40R30	R41224	T40189
		R40F3Y	R40R3E	R4125N	T4019R
		R40F7Z	R40R6N	R41336	T4019U
		R40G32	R40R80	R4133U	T4028N
		R40G33	R40T0C	R41385	T5A311
		R40G47	R40T0L	R4138L	T5A48U
		R40G79	R40T1K	R4142V	T5A74C
		R40G8A	R40T1L		
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (33mm)	CDH33A	R4075V	R40F8Z	R40P9C	R4146W
		R4075X	R40G3P	R40R3F	R41579
		R4077T	R40G4X	R40U2P	R4170T
		R40781	R40H1A	R40U2W	R41756
		R40974	R40J0A	R40W1E	R4183E
		R40A5L	R40J0H	R40X1X	R41878
		R40A9W	R40K31	R40X70	R5759V
		R40D5R	R40K32	R40Z81	R5AD34
		R40D9T	R40L8Z	R4112V	R5AY5V
		R40E2F	R40M5X	R41189	T4022H
		R40E86	R40N54	R4121C	T4028H
		R40F61	R40N8G	R4137D	T4037C
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (21mm)	ECS21A	R93480	R9463Z	R94V8P	T92194
		R9371K	R94G5T	R95335	T9235W
		R93V70			
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (25mm)	ECS25A	R92T17	R93K1K	R94H82	R95616
		R92T18	R93M5L	R94K3K	R9569P
		R92X8A	R93Y34	R94P6G	R9573Y
		R9323R	R9421G	R94U73	R9589U
		R93483	R9474D	R94Z5W	T9233D
		R93C6D	R94D3V	R9503N	T9234N
		R93J6K	R94G76	R95155	
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (29mm)	ECS29A	R92L8F	R93D2X	R9477T	R94Z20
		R92R99	R93H38	R9477U	R94Z87
		R92T1A	R93J36	R9493W	R9503P
		R92T41	R93J6H	R9495C	R95157
		R92U1T	R93K4N	R9495L	R95218
		R92U4H	R93K4P	R94D21	R9524L
		R92U4N	R93L86	R94D8W	R95514
		R92V53	R93P3K	R94G5X	R95515
		R92W3F	R93T9M	R94G8L	R9571Z
		R92X9L	R93V2T	R94J4H	R9584A
R92Y3M	R93X7D	R94K1R	R95902		

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Product Name	Product Code	Lot#			
		R9312M	R93X9T	R94M1F	T9224W
		R93151	R93Y33	R94P6F	T9224X
		R9354N	R93Z1M	R94R76	T9228Z
		R9357A	R94071	R94T0Z	T9235X
		R9385H	R9432H	R94W19	T9249D
		R9398G	R9437K	R94W7D	T9251M
		R93C7N	R9438T	R94Y07	T9280E
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (33mm)	ECS33A	R92T1C	R93K9L	R9468A	R94N5P
		R92U76	R9401Y	R94G8M	R95720
		R93895	R94242		

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 any product subject to this action has been forwarded to another facility, contact that facility to make them aware of the Field Safety Notice.
3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and send to [Suzan AlDawalibi – 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 Field Safety Notice.**
4. Customers are required to return all unused Intraluminal Stapler (ILS) or kits subject to this recall that are in their inventory when product supply at their hospital or facility has been reestablished.
5. Returned items should be locally destructed to be eligible for replacement/credit notes.

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.

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 saldawal@its.jnj.com

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 lot numbers of Intraluminal Staplers (ILS) subject to this Field Safety Corrective Action by using the packaging labels. Please refer to table above for a list of all product codes with lot numbers subject to this Voluntary Product Recall.

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



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FRONT OF SINGLE UNIT TYVEK



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ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this Field Safety Notice is requested.

Please complete and send this form to [saldawal@its.jni.com] within 3 business days, even if you do not have product subject to this Field Safety Corrective Action to return.

If you have product subject to the voluntary product recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return, thank you for your cooperation.

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

PRODUCT NAME	PRODUCT CODE	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		

Account Name: _____

Account Address: _____

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Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Signed*: <i>* Your signature provides confirmation that you have received and understood this notification</i>	
<i>Your comments are welcome.</i>	