

## URGENT: MEDICAL DEVICE FIELD ACTION (NOTIFICATION)

### Intraluminal Staplers (ILS)

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

03-Apr-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.

Ethicon has initiated a medical device Field Action (notification) of 701 (WW) lots of Intraluminal Staplers (ILS). Through investigation of complaints and returned products, Ethicon has confirmed occurrence of uncut washers and malformed staples with their 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 **Attachment 3** 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, healthcare professionals can choose to continue using the products subject to this notification, whilst taking note of the following recommendations stated. 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.



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- 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.

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

**The scope of this Field Action includes ALL Intraluminal Staplers (ILS) from the product codes and lot numbers listed in Attachment 3.**

#### **ACTION REQUIRED:**

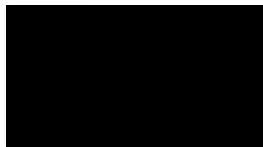
1. Ethicon is requesting that you examine your inventory to determine if you may have impacted product. Refer to **Attachment 1** for the Product Identification Tool to identify the products that are subject to this Field Action (notification) by using package labels.
2. If you have alternative product available, please return all products subject to this notification (Reference **Attachment 3** 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 return it to your Ethicon Sales Representative within three (3) business days. **Please return the BRF even if you do not have the product lots subject to this notification.**
5. To return product subject to this action, please contact your Ethicon Sales Representative.
6. If you are returning impacted product in your inventory, please contact your Ethicon Sales Representative for replacement/credit matters.



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If you have additional questions regarding this field action or to report any customer complaints, please contact your Ethicon Sales Representative.

Yours sincerely,



Lee Ching Hwee  
Manager, Regulatory Affairs

cc: Chairman Medical Board  
Relevant Head of Departments

**ATTACHMENTS:**

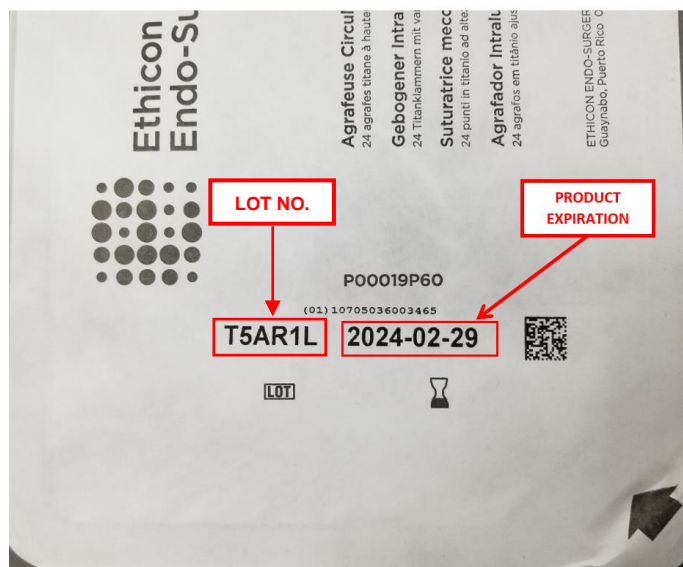
Attachment 1: Product Identification Tool  
Attachment 2: Business Reply Form (BRF)

## 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 notification by using the packaging labels. Please refer to **Attachment 3** for a list of all product codes and lot numbers subject to this notification.

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

#### FRONT OF SINGLE UNIT CARTON



## ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and hand this form to your Ethicon sales representative **within 3 business days, even if you do not have the product subject to this field action to return.**

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

- ☐ 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:**

- ☐ 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 supply of alternative product and we chose to continue to use the product, whilst taking note of the recommendations stated in this notice. 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 Code	Lot No.	Quantity in stock	Quantity Returning	Stock or Consignment

Name, Sign and Date <i>(Person Completing Business Reply Form):</i>	Customer Account Details <i>(Name and Address):</i>
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**ATTACHMENT 3: Product Subject to this Field Action**

CDH21A			21mm Curved Intraluminal Stapler		
Lot numbers					
R40718	R40A9Y	R40C0X	R40D5T	R40E9V	R40F08
R40H0Z	R40H10	R40K1C	R40K1D	R40L7V	R40M38
R40N7T	R40U9C	R40U9V	R40W1R	R40W23	R40X1T
R40Y00	R40Y8L	R40Z2U	R40Z4V	R41199	R4119A
R4126L	R4126M	R5762R	R5AD4T		

CDH25A			25mm Curved Intraluminal Stapler		
Lot numbers					
R40702	R40F1M	R40M0T	R40V88	R41283	R57549
R4073N	R40F36	R40M2N	R40V9A	R41292	R5754A
R4073T	R40F3C	R40M52	R40W2R	R4129H	R5AC9G
R4074U	R40F4H	R40M5E	R40W37	R4129J	R5AN6C
R4074V	R40F4J	R40M9X	R40W7J	R4130W	R5AT4W
R4086C	R40F5T	R40N08	R40W8K	R4130X	R5AX2D
R4086K	R40G2X	R40N56	R40W8Y	R4135T	R5C003
R4086M	R40G3A	R40N5E	R40X3D	R4140N	R5C32J
R40A0D	R40G3C	R40N6Y	R40X3N	R41485	T4016T
R40A0Y	R40H19	R40N78	R40X5W	R41491	T40170
R40A0Z	R40H3T	R40N79	R40X6K	R4149J	T4022F
R40A50	R40H3U	R40P7G	R40X6L	R4152G	T4025P
R40A51	R40J05	R40P80	R40X7U	R4154K	T4025R
R40C06	R40J0L	R40R5H	R40Y0L	R4154L	T40333
R40C9F	R40J0U	R40R5T	R40Y7W	R41601	T4033G
R40C9G	R40J0V	R40R67	R40Z13	R41613	T40359
R40D29	R40J2A	R40R6F	R40Z50	R41642	T4056Y
R40D2F	R40J7T	R40T7G	R40Z8F	R41643	T40576
R40D2G	R40K56	R40T7H	R41083	R4164M	T5A18K
R40D8Y	R40L0H	R40T8A	R41087	R4165C	T5A53R
R40E7A	R40L12	R40T8T	R4108M	R4176R	T5A79M
R40E7K	R40L3P	R40U1W	R4109N	R4177K	T5A98J
R40E7X	R40L5D	R40U24	R4114Z	R4178J	T5AH2G
R40F0D	R40L81	R40U2R	R4117P	R41799	T5AM5V
R40F0K	R40M0R	R40V82	R4117X	R4190E	



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CDH29A			29mm Curved Intraluminal Stapler		
Lot numbers					
R4073X	R40743	R4074A	R4078C	R4078D	R4078E
R4080X	R40812	R40813	R40819	R4081K	R4081R
R40833	R4083F	R40862	R40863	R4096J	R4096R
R4096Y	R4099T	R40A0A	R40A1E	R40A1F	R40A59
R40A63	R40A6J	R40A88	R40A8U	R40C18	R40C93
R40D0T	R40D0V	R40D62	R40D6K	R40D6T	R40D71
R40D7D	R40D8F	R40D95	R40D9N	R40E2A	R40E2V
R40E2W	R40E3L	R40E3Z	R40E48	R40E5Y	R40E6T
R40F3X	R40F3Y	R40F4X	R40F5N	R40F7Z	R40F85
R40F8F	R40G32	R40G33	R40G47	R40G79	R40G8A
R40G91	R40G97	R40G9N	R40H01	R40H08	R40H6V
R40H6W	R40H7H	R40H8C	R40H8M	R40H92	R40H9E
R40H9X	R40J2K	R40J39	R40J3Z	R40J8G	R40J9A
R40J9D	R40J9J	R40K50	R40K51	R40K7K	R40K7T
R40K7U	R40K82	R40K83	R40L3V	R40L3Z	R40L4V
R40L57	R40L8V	R40L9A	R40L9J	R40M07	R40M0P
R40M13	R40M22	R40M2A	R40M5U	R40N0R	R40N19
R40N52	R40N53	R40N5J	R40N6J	R40N81	R40N86
R40N8N	R40N8P	R40P1Z	R40P23	R40P24	R40P84
R40P9Z	R40R0H	R40R2Z	R40R30	R40R3E	R40R6N
R40R7U	R40R80	R40T0C	R40T0L	R40T1K	R40T1L
R40T1V	R40T48	R40T4E	R40T4F	R40T7X	R40T84
R40T9H	R40U1H	R40U1N	R40U4F	R40U4L	R40V0C
R40V36	R40V8F	R40V94	R40V9U	R40W0E	R40W0Z
R40W1A	R40W28	R40W5T	R40W5Y	R40W96	R40X1C
R40X1J	R40X3Z	R40X40	R40X5F	R40X7L	R40X7M
R40Y4J	R40Y4K	R40Y7E	R40Y7F	R40Z0L	R40Z0X
R40Z4X	R40Z7R	R40Z7T	R40Z7V	R4105G	R4106V
R41073	R41125	R4112C	R41133	R41134	R41150
R4115X	R41164	R4117L	R4117M	R41194	R4119Z
R41205	R4121M	R4121N	R41224	R4125N	R41262
R41309	R4132T	R4132U	R41336	R4133T	R4133U
R4137L	R41385	R4138L	R4142U	R4142V	R41444
R41448	R4145D	R4145G	R4145H	R4149D	R4152W
R4152Z	R41538	R4153Y	R41564	R41565	R41572



Cont'd

CDH29A			29mm Curved Intraluminal Stapler		
Lot numbers					
R4165H	R41661	R41666	R4167G	R4167H	R4168W
R4168X	R4168Y	R41703	R4170F	R4172U	R4175Y
R41762	R4177Y	R4177Z	R4183F	R4186N	R4186W
R4190F	R4190R	R4190T	R41917	R4193C	R41947
R41962	R5756Z	R5AE8R	R5AM2J	R5AW3N	R5C435
R5C505	T40014	T4007L	T4007R	T40080	T4009W
T40173	T4017F	T40189	T4018C	T4018R	T4019R
T4019U	T4022M	T4025J	T4026E	T40270	T4028N
T4030X	T4031F	T4040N	T4040Y	T40425	T4042M
T4060X	T4061Y	T4062L	T4064X	T4066K	T4066L
T5A311	T5A48U	T5A74C	T5AE4P	T5AF3C	T5AK4K
T5AK8L	T5AL3N	T5AL8M			

CDH33A			33mm Curved Intraluminal Stapler		
Lot numbers					
R4075V	R4075X	R4077T	R40781	R40974	R40A5L
R40A5X	R40A9W	R40D5R	R40D63	R40D9T	R40E2F
R40E86	R40F4N	R40F61	R40F8Y	R40F8Z	R40G3P
R40G4W	R40G4X	R40H1A	R40J0A	R40J0H	R40K31
R40K32	R40L8Z	R40M5X	R40N54	R40N8G	R40P9C
R40R3F	R40U2P	R40U2W	R40W1E	R40X1X	R40X70
R40Z81	R4112V	R41189	R4121C	R4137C	R4137D
R4146W	R4146X	R41579	R4170T	R41756	R4183E
R41878	R5759V	R5AD34	R5AY5V	T4016L	T4022G
T4022H	T4028H	T4037C	T4037N	T4060W	T40639
T4065R					

ECS21A			21mm Endoscopic Curved Intraluminal Stapler		
Lot numbers					
R93480	R9371K	R93V70	R9463Z	R94G5T	R94V8P
R95335	T92194	T9235W			



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ECS25A			25mm Endoscopic Curved Intraluminal Stapler		
Lot numbers					
R92T17	R92T18	R92X50	R92X8A	R9323R	R9328C
R93483	R93484	R93C6D	R93C73	R93J6J	R93J6K
R93K1K	R93M5L	R93M85	R93Y34	R9421G	R9421M
R9474D	R94D3V	R94D3W	R94G76	R94H82	R94K3K
R94P3T	R94P6G	R94U73	R94Z5W	R9503N	R95155
R95616	R9569P	R9573Y	R9589U	T9233D	T9234N
T92631	T92F8E	T92G0K			

ECS29A			29mm Endoscopic Curved Intraluminal Stapler		
Lot numbers					
R92L8F	R92N80	R92R99	R92T1A	R92T41	R92U1T
R92U4H	R92U4N	R92V53	R92W3F	R92X9L	R92Y2R
R92Y3M	R9312M	R93151	R93481	R9354N	R9357A
R9385H	R9385J	R9398G	R9399F	R93C7N	R93D2X
R93D2Y	R93H38	R93J36	R93J6H	R93K4N	R93K4P
R93L86	R93L9Y	R93M1K	R93N35	R93P3K	R93T9M
R93V2T	R93X7D	R93X9T	R93Y33	R93Z1M	R94071
R9432H	R9437K	R9438T	R9477T	R9477U	R9493W
R9495C	R9495L	R94D21	R94D8W	R94G5X	R94G8L
R94J4H	R94K1R	R94K1T	R94M1F	R94P3U	R94P6F
R94R76	R94T0Z	R94U47	R94W19	R94W1A	R94W7D
R94Y07	R94Z20	R94Z87	R9503P	R95157	R95218
R9524L	R95255	R95514	R95515	R9571Z	R9584A
R9589N	R95902	T9224W	T9224X	T9228Z	T9235X
T9249D	T9251M	T9272L	T9280C	T9280E	T9291P
T92949	T92E5W	T92E5X	T92G4M	T92K38	

ECS33A			33mm Endoscopic Curved Intraluminal Stapler		
Lot numbers					
R92T1C	R92U76	R93895	R93K9L	R9401Y	R94242
R9468A	R94G8M	R94N5P	R95720	T9272M	T92G0Z

SDH21A			21mm Straight Intraluminal Stapler		
Lot numbers					
R40X34					

SDH25A			25mm Straight Intraluminal Stapler		
Lot numbers					
R40A31	R40A5Y	R40D84	R40D85	R40J6K	R40M2P
R40N43	R40P93	R40W6A	R40W7D	R41710	R4184C
T40662	T40663				

SDH29A			29mm Straight Intraluminal Stapler		
Lot numbers					
R40C09	R40D6G	R40F7H	R40J0P	R40K8R	R40M6K
R40M9L	R40N48	R40U3Z	R40V38	R4120K	R4171H
T4053Y	T4053Z				

-- END --