

URGENT: FIELD SAFETY NOTICE

Intraluminal Staplers (ILS)

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

March XX, 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 Safety Corrective Action of **378 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 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.

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

- 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 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 CDH21AU	R40718	R40K1D	R40U9V	R41199
		R40C0X	R40L7V	R40X1T	R5762R
		R40E9V	R40M38	R40Z4V	R5AD4T
		R40H10			
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (25mm)	CDH25A CDH25AU	R40702	R40G3A	R40R67	R57549
		R4073T	R40H19	R40T7H	R5754A
		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 CDH29AU	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
				R40K51	R40W1A

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Product Name	Product Code	Lot#			
		R4096Y			
		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
		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 CDH33AU	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
			ECS21A	R93480	R9463Z

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Product Name	Product Code	Lot#			
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (21mm)		R9371K	R94G5T	R95335	T9235W
		R93V70			
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (25mm)	ECS25A ECS25AU	R92T17	R93K1K	R94H82	R95616
		R92T18	R93M5L	R94K3K	R9569P
		R92X8A	R93Y34	R94P6G	R9573Y
		R9323R	R9421G	R94U73	R9589U
		R93483	R9474D	R94Z5W	T9233D
		R93C6D	R94D3V	R9503N	T9234N
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (29mm)	ECS29A ECS29AU	R93J6K	R94G76	R95155	
		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
		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 ECS33AU	R92T1C	R93K9L	R9468A	R94N5P
		R92U76	R9401Y	R94G8M	R95720
		R93895	R94242		

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Table 2. Kit Codes with affected Lots to this notification

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
CK00265	10111162	CK00265	10098271	CK00265	10109061	CK00265	10123837
CK00265	10111160	CK00265	10098272	CK00265	10109063	CK00265	10123836
CK00265	10111166	CK00265	10098278	CK00265	10109060	CK00265	10123814
CK00265	10111170	CK00265	10098270	CK00265	10110348	CK00265	10123812
CK00265	10111168	CK00265	10098277	CK00265	10117090	CK00265	10123813
CK00265	10111159	CK00265	10098276	CK00265	10117095	CK00265	10125774
CK00265	10112440	CK00265	10099545	CK00265	10117094	CK00265	10125777
CK00265	10112439	CK00265	10099546	CK00265	10117091	CK00265	10125776
CK00265	10112436	CK00265	10099548	CK00265	10117092	CK00265	10125775
CK00265	10112437	CK00265	10104702	CK00265	10121148	CK00265	10127691
CK00265	10112438	CK00265	10104696	CK00265	10121150	CK00265	10127682
CK00265	10097993	CK00265	10104704	CK00265	10121146	CK00265	10127684
CK00265	10097991	CK00265	10104698	CK00265	10121145	CK00265	10127694
CK00265	10097995	CK00265	10104707	CK00265	10121149	CK00265	10127678
LCOL102	10105193	LCOL102	10105201	LCOL102	10105205	LCOL102	10105210
LCOL104	10090927	LCOL104	10098249	LCOL104	10106011	LCOL104	10121797
LCOL104	10090934	LCOL104	10099909	LCOL104	10106028	LCOL104	10121812
LCOL104	10090939	LCOL104	10099911	LCOL104	10106205	LCOL104	10121817
LCOL104	10090958	LCOL104	10099912	LCOL104	10106208	LCOL104	10123553
LCOL104	10095621	LCOL104	10099913	LCOL104	10106211	LCOL104	10123556
LCOL104	10095624	LCOL104	10101809	LCOL104	10106214	LCOL104	10123586
LCOL104	10095642	LCOL104	10101813	LCOL104	10109217	LCOL104	10123614
LCOL104	10095646	LCOL104	10101820	LCOL104	10109226	LCOL104	10124487
LCOL104	10097826	LCOL104	10101825	LCOL104	10109236	LCOL104	10124492
LCOL104	10097830	LCOL104	10103132	LCOL104	10109271	LCOL104	10124500
LCOL104	10097854	LCOL104	10103138	LCOL104	10118509	LCOL104	10124508
LCOL104	10097858	LCOL104	10103144	LCOL104	10118511	LCOL104	10127727
LCOL104	10098162	LCOL104	10103151	LCOL104	10118513	LCOL104	10127733
LCOL104	10098168	LCOL104	10105990	LCOL104	10118517	LCOL104	10127738
LCOL104	10098239	LCOL104	10105995	LCOL104	10121777	LCOL104	10127749
LCOL105	10113514	LCOL105	10099712	LCOL105	10106057	LCOL105	10119862
LCOL105	10113502	LCOL105	10100695	LCOL105	10106068	LCOL105	10119863
LCOL105	10113509	LCOL105	10100702	LCOL105	10110383	LCOL105	10119887
LCOL105	10113518	LCOL105	10100710	LCOL105	10110391	LCOL105	10121857
LCOL105	10094778	LCOL105	10100719	LCOL105	10110399	LCOL105	10121874
LCOL105	10094782	LCOL105	10102656	LCOL105	10110406	LCOL105	10121887

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL105	10094789	LCOL105	10102661	LCOL105	10114881	LCOL105	10121898
LCOL105	10094797	LCOL105	10102664	LCOL105	10114885	LCOL105	10123592
LCOL105	10096163	LCOL105	10102667	LCOL105	10114892	LCOL105	10123600
LCOL105	10096169	LCOL105	10102764	LCOL105	10114897	LCOL105	10123604
LCOL105	10096176	LCOL105	10102784	LCOL105	10115919	LCOL105	10123610
LCOL105	10096191	LCOL105	10102808	LCOL105	10115943	LCOL105	10126553
LCOL105	10097315	LCOL105	10102830	LCOL105	10115948	LCOL105	10126585
LCOL105	10097323	LCOL105	10104135	LCOL105	10115951	LCOL105	10126607
LCOL105	10097328	LCOL105	10104140	LCOL105	10115899	LCOL105	10126620
LCOL105	10097342	LCOL105	10104143	LCOL105	10115903	LCOL105	10128123
LCOL105	10099704	LCOL105	10104146	LCOL105	10115905	LCOL105	10128127
LCOL105	10099707	LCOL105	10106024	LCOL105	10115909	LCOL105	10128131
LCOL105	10099709	LCOL105	10106039	LCOL105	10119859	LCOL105	-
LCOL108P	10092854	LCOL108P	10103519	LCOL108P	10115761	LCOL108P	10119069
LCOL108P	10092881	LCOL108P	10103526	LCOL108P	10115774	LCOL108P	10119075
LCOL108P	10092886	LCOL108P	10103539	LCOL108P	10115781	LCOL108P	10119079
LCOL108P	10092892	LCOL108P	10103548	LCOL108P	10115791	LCOL108P	10119083
LCOL110	10094647	LCOL110	10094664	LCOL110	10111687	LCOL110	10122367
LCOL110	10094654	LCOL110	10111641	LCOL110	10111691	LCOL110	10122374
LCOL110	10094657	LCOL110	10111684	LCOL110	10122352	LCOL110	10122390
LCOL111P	10096190	LCOL111P	10096202	LCOL111P	10101744	LCOL111P	10114027
LCOL111P	10096196	LCOL111P	10101732	LCOL111P	10101749	LCOL111P	10114029
LCOL111P	10096199	LCOL111P	10101739	LCOL111P	10114024	LCOL111P	10114040
LCOL113	10098974	LCOL113	10100906	LCOL113	10108323	LCOL113	10109639
LCOL113	10098991	LCOL113	10100911	LCOL113	10108357	LCOL113	10109650
LCOL113	10099539	LCOL113	10108301	LCOL113	10108384	LCOL113	10112545
LCOL113	10099542	LCOL113	10108314	LCOL113	10108399	LCOL113	10112551
LCOL113	10099543	LCOL113	10108318	LCOL113	10109621	LCOL113	10112554
LCOL113	10099549	LCOL113	10108320	LCOL113	10109629	LCOL113	10112558
LCOL113	10100899	LCOL113	-	LCOL113	-	LCOL113	-
LCOL115	10091325	LCOL115	10095687	LCOL115	10102210	LCOL115	10117971
LCOL115	10091428	LCOL115	10095689	LCOL115	10102226	LCOL115	10117975
LCOL115	10091432	LCOL115	10100482	LCOL115	10102234	LCOL115	10126629
LCOL115	10091433	LCOL115	10100484	LCOL115	10102237	LCOL115	10126670
LCOL115	10095674	LCOL115	10100485	LCOL115	10117965	LCOL115	10126681
LCOL115	10095682	LCOL115	10100487	LCOL115	10117969	LCOL115	10126694
LCOL117	10093981	LCOL117	10094000	LCOL117	10096800	LCOL117	10096817
LCOL117	10093986	LCOL117	10094018	LCOL117	10096809	LCOL117	10096825

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL120	10088202	LCOL120	10094822	LCOL120	10112453	LCOL120	10128091
LCOL120	10088208	LCOL120	10094832	LCOL120	10112457	LCOL120	10128098
LCOL120	10088212	LCOL120	10097853	LCOL120	10112461	LCOL120	10128022
LCOL120	10088266	LCOL120	10097862	LCOL120	10112468	LCOL120	10128037
LCOL120	10094795	LCOL120	10097868	LCOL120	10128039	LCOL120	10128106
LCOL120	10094809	LCOL120	10097875	LCOL120	10128085	LCOL120	10128108
LCOL124	10087629	LCOL124	10098263	LCOL124	10106971	LCOL124	10115762
LCOL124	10087601	LCOL124	10098274	LCOL124	10106980	LCOL124	10115765
LCOL124	10087615	LCOL124	10098285	LCOL124	10106981	LCOL124	10115771
LCOL124	10087621	LCOL124	10098289	LCOL124	10106990	LCOL124	10115777
LCOL124	10087635	LCOL124	10098292	LCOL124	10107002	LCOL124	10117851
LCOL124	10095680	LCOL124	10098375	LCOL124	10107005	LCOL124	10117868
LCOL124	10095685	LCOL124	10101622	LCOL124	10107011	LCOL124	10117875
LCOL124	10095700	LCOL124	10101625	LCOL124	10112176	LCOL124	10117879
LCOL124	10095702	LCOL124	10101629	LCOL124	10112199	LCOL124	10121492
LCOL124	10095704	LCOL124	10101643	LCOL124	10112207	LCOL124	10121500
LCOL124	10095706	LCOL124	10101649	LCOL124	10112227	LCOL124	10121501
LCOL124	10095709	LCOL124	10101653	LCOL124	10112188	LCOL124	10121508
LCOL124	10095714	LCOL124	10101659	LCOL124	10112241	LCOL124	10121511
LCOL124	10098229	LCOL124	10101667	LCOL124	10112355	LCOL124	10121521
LCOL124	10098235	LCOL124	10106963	LCOL124	10112365	LCOL124	10121524
LCOL124	10121533	LCOL124	-	LCOL124	-	LCOL124	-
LCOL126	10110523	LCOL126	10110501	LCOL126	10119854	LCOL126	10119879
LCOL126	10110497	LCOL126	10110510	LCOL126	10119861	LCOL126	10119890
LCOL127	10108061	LCOL127	10108088	LCOL127	10128369	LCOL127	10128406
LCOL127	10108064	LCOL127	10108095	LCOL127	10128376	LCOL127	10128419
LCOL127	10108081	LCOL127	10108096	LCOL127	10128383	LCOL127	10128429
LCOL127	10108084	LCOL127	10108102	LCOL127	10128386	LCOL127	10128439
LCOL135	10095106	LCOL135	10095111	LCOL135	10095116	LCOL135	10095121
LCOL135	10095108	LCOL135	10095113	LCOL135	-	LCOL135	-
LCOL137	10114286	LCOL137	10114296	LCOL137	10124961	LCOL137	10124968
LCOL137	10114293	LCOL137	10114305	LCOL137	10124966	LCOL137	10124971
LCOL138	10121256	LCOL138	10121264	LCOL138	10123574	LCOL138	10124819
LCOL138	10121259	LCOL138	10123565	LCOL138	10123578	LCOL138	10124824
LCOL138	10121262	LCOL138	10123569	LCOL138	10124814	LCOL138	10124829
LCOL139	10116066	LCOL139	10116089	LCOL139	10129309	LCOL139	10129317
LCOL139	10116081	LCOL139	10116116	LCOL139	10129313	LCOL139	10129322
LCOL55P	10093213	LCOL55P	10102162	LCOL55P	10113971	LCOL55P	10124039

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL55P	10093221	LCOL55P	10102168	LCOL55P	10113976	LCOL55P	10124049
LCOL55P	10101084	LCOL55P	10102175	LCOL55P	10113984	LCOL55P	10124055
LCOL55P	10101093	LCOL55P	10102181	LCOL55P	10113986	LCOL55P	10124059
LCOL55P	10101095	LCOL55P	10102186	LCOL55P	10113990	LCOL55P	10124063
LCOL55P	10101099	LCOL55P	10105562	LCOL55P	10113992	LCOL55P	10124064
LCOL55P	10102147	LCOL55P	10105570	LCOL55P	10113996	LCOL55P	10124066
LCOL55P	10102157	LCOL55P	10105579	LCOL55P	10114001	LCOL55P	10124079
LCOL55P	10102161	LCOL55P	10105591	LCOL55P	-	LCOL55P	-
LCOL56P	10114871	LCOL56P	10094896	LCOL56P	10107821	LCOL56P	10114865
LCOL56P	10114874	LCOL56P	10094903	LCOL56P	10107827	LCOL56P	10114868
LCOL56P	10115217	LCOL56P	10094930	LCOL56P	10112001	LCOL56P	10126094
LCOL56P	10115230	LCOL56P	10094937	LCOL56P	10112160	LCOL56P	10126103
LCOL56P	10115238	LCOL56P	10107805	LCOL56P	10112163	LCOL56P	10126108
LCOL56P	10115244	LCOL56P	10107810	LCOL56P	10112175	LCOL56P	10126114
LCOL58	10114576	LCOL58	10103491	LCOL58	10089230	LCOL58	10116438
LCOL58	10114627	LCOL58	10103503	LCOL58	10089231	LCOL58	10116448
LCOL58	10114637	LCOL58	10103507	LCOL58	10089237	LCOL58	10124461
LCOL58	10093269	LCOL58	10103513	LCOL58	10089238	LCOL58	10124468
LCOL58	10093282	LCOL58	10085040	LCOL58	10089245	LCOL58	10124471
LCOL58	10093288	LCOL58	10085044	LCOL58	10089246	LCOL58	10124474
LCOL58	10093299	LCOL58	10085049	LCOL58	10089251	LCOL58	10126085
LCOL58	10095572	LCOL58	10085051	LCOL58	10114677	LCOL58	10126098
LCOL58	10095577	LCOL58	10085052	LCOL58	10116325	LCOL58	10126101
LCOL58	10095584	LCOL58	10085822	LCOL58	10116326	LCOL58	10126107
LCOL58	10095588	LCOL58	10085826	LCOL58	10116328	LCOL58	10126110
LCOL58	10096116	LCOL58	10085831	LCOL58	10116332	LCOL58	10126113
LCOL58	10096119	LCOL58	10085844	LCOL58	10116334	LCOL58	10126116
LCOL58	10096123	LCOL58	10089163	LCOL58	10116339	LCOL58	10126118
LCOL58	10096126	LCOL58	10089170	LCOL58	10116344	LCOL58	10126120
LCOL58	10103475	LCOL58	10089190	LCOL58	10116403	LCOL58	10126124
LCOL58	10103480	LCOL58	10089208	LCOL58	10116417	LCOL58	10126129
LCOL58	10103485	LCOL58	10089214	LCOL58	10116427	LCOL58	10126141
LCOL58	10103487	LCOL58	-	LCOL58	-	LCOL58	-
LCOL59P	10096180	LCOL59P	10102867	LCOL59P	10102889	LCOL59P	10124675
LCOL59P	10096184	LCOL59P	10102876	LCOL59P	10109541	LCOL59P	10124684
LCOL59P	10096194	LCOL59P	10102881	LCOL59P	10124671	LCOL59P	10124690
LCOL59P	10096207	LCOL59P	-	LCOL59P	-	LCOL59P	-
LCOL63P	10099529	LCOL63P	10102067	LCOL63P	10109548	LCOL63P	10106738

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL63P	10099533	LCOL63P	10102068	LCOL63P	10109555	LCOL63P	10106811
LCOL63P	10099536	LCOL63P	10102072	LCOL63P	10109559	LCOL63P	10106871
LCOL63P	10102066	LCOL63P	-	LCOL63P	-	LCOL63P	-
LCOL71	10094966	LCOL71	10101386	LCOL71	10114878	LCOL71	10122331
LCOL71	10094950	LCOL71	10101390	LCOL71	10114888	LCOL71	10122336
LCOL71	10094954	LCOL71	10103588	LCOL71	10114894	LCOL71	10123142
LCOL71	10094961	LCOL71	10103591	LCOL71	10114899	LCOL71	10123149
LCOL71	10096162	LCOL71	10103598	LCOL71	10115851	LCOL71	10123151
LCOL71	10096166	LCOL71	10103605	LCOL71	10115864	LCOL71	10123152
LCOL71	10096177	LCOL71	10104833	LCOL71	10115878	LCOL71	10125079
LCOL71	10096182	LCOL71	10104888	LCOL71	10115890	LCOL71	10125082
LCOL71	10098148	LCOL71	10104904	LCOL71	10118720	LCOL71	10125085
LCOL71	10098155	LCOL71	10104906	LCOL71	10118725	LCOL71	10125088
LCOL71	10098158	LCOL71	10106445	LCOL71	10118727	LCOL71	10125559
LCOL71	10098248	LCOL71	10106447	LCOL71	10118731	LCOL71	10125566
LCOL71	10099225	LCOL71	10106450	LCOL71	10119698	LCOL71	10125570
LCOL71	10099210	LCOL71	10106453	LCOL71	10119703	LCOL71	10125575
LCOL71	10099214	LCOL71	10108359	LCOL71	10119711	LCOL71	10127712
LCOL71	10099218	LCOL71	10108369	LCOL71	10119718	LCOL71	10127719
LCOL71	10100887	LCOL71	10108380	LCOL71	10120469	LCOL71	10127725
LCOL71	10100893	LCOL71	10108387	LCOL71	10120477	LCOL71	10127730
LCOL71	10100897	LCOL71	10110174	LCOL71	10120494	LCOL71	10128346
LCOL71	10100900	LCOL71	10110183	LCOL71	10120502	LCOL71	10128350
LCOL71	10101377	LCOL71	10110199	LCOL71	10122322	LCOL71	10128355
LCOL71	10101382	LCOL71	10110209	LCOL71	10122327	LCOL71	10128362
LCOL76	10091054	LCOL76	10094675	LCOL76	10105873	LCOL76	10116945
LCOL76	10091060	LCOL76	10097836	LCOL76	10105875	LCOL76	10116949
LCOL76	10091064	LCOL76	10097841	LCOL76	10110382	LCOL76	10116956
LCOL76	10091067	LCOL76	10097842	LCOL76	10110396	LCOL76	10116964
LCOL76	10093308	LCOL76	10097855	LCOL76	10110402	LCOL76	10117015
LCOL76	10093312	LCOL76	10097834	LCOL76	10110410	LCOL76	10117020
LCOL76	10093318	LCOL76	10097845	LCOL76	10110419	LCOL76	10117040
LCOL76	10093325	LCOL76	10097850	LCOL76	10110475	LCOL76	10122164
LCOL76	10094652	LCOL76	10097955	LCOL76	10110482	LCOL76	10122167
LCOL76	10094659	LCOL76	10105870	LCOL76	10110490	LCOL76	10122171
LCOL76	10094668	LCOL76	10105872	LCOL76	10116940	LCOL76	10122173
LCOL78	10087604	LCOL78	10087612	LCOL78	10106219	LCOL78	10106225
LCOL78	10087610	LCOL78	10087618	LCOL78	10106223	LCOL78	-

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL79	10123248	LCOL79	10123254	LCOL79	10123265	LCOL79	10123290
LCOL82	10099474	LCOL82	10100715	LCOL82	10106419	LCOL82	10121085
LCOL82	10099475	LCOL82	10106375	LCOL82	10106427	LCOL82	10121092
LCOL82	10099480	LCOL82	10106381	LCOL82	10114692	LCOL82	10121093
LCOL82	10099485	LCOL82	10106389	LCOL82	10114701	LCOL82	10121094
LCOL82	10100690	LCOL82	10106396	LCOL82	10114717	LCOL82	10121095
LCOL82	10100699	LCOL82	10106403	LCOL82	10114731	LCOL82	10121100
LCOL82	10100709	LCOL82	10106414	LCOL82	10121084	LCOL82	10121108
LCOL86	10093322	LCOL86	10093363	LCOL86	10093368	LCOL86	10093377
LCOL86	10093331	LCOL86	10093366	LCOL86	10093370	LCOL86	10093387
LCOL87	10090359	LCOL87	10090892	LCOL87	10103563	LCOL87	10103573
LCOL87	10090369	LCOL87	10090923	LCOL87	10103567	LCOL87	10103576
LCOL87	10090888	LCOL87	10090926	LCOL87	-	LCOL87	-
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	LCOL89	-
LCOL92P	10104562	LCOL92P	10107559	LCOL92P	10114525	LCOL92P	10122913
LCOL92P	10104580	LCOL92P	10107567	LCOL92P	10114534	LCOL92P	10122922
LCOL92P	10104598	LCOL92P	10110596	LCOL92P	10114539	LCOL92P	10125574
LCOL92P	10104606	LCOL92P	10110601	LCOL92P	10114548	LCOL92P	10125583
LCOL92P	10107542	LCOL92P	10110602	LCOL92P	10122897	LCOL92P	10125591
LCOL92P	10107552	LCOL92P	10110608	LCOL92P	10122908	LCOL92P	10125599
LCOL99	10096436	LCOL99	10096499	LCOL99	10104575	LCOL99	10119700
LCOL99	10096460	LCOL99	10096557	LCOL99	10104546	LCOL99	10119706
LCOL99	10096471	LCOL99	10096568	LCOL99	10104554	LCOL99	10119709
LCOL99	10096487	LCOL99	10096592	LCOL99	10104565	LCOL99	10119715
LCOLB122	10098439	LCOLB122	10099906	LCOLB122	10109275	LCOLB122	10109545
LCOLB122	10098451	LCOLB122	10099910	LCOLB122	10109279	LCOLB122	10109549
LCOLB122	10098456	LCOLB122	10109229	LCOLB122	10109293	LCOLB122	10109550
LCOLB122	10098475	LCOLB122	10109238	LCOLB122	10109339	LCOLB122	10109552
LCOLB122	10098463	LCOLB122	10109240	LCOLB122	10109526	LCOLB122	10109556
LCOLB122	10098484	LCOLB122	10109251	LCOLB122	10109537	LCOLB122	10109561
LCOLB122	10098499	LCOLB122	10109250	LCOLB122	10109539	LCOLB122	10109551
LCOLB122	10098507	LCOLB122	10109260	LCOLB122	10109540	LCOLB122	10109558
LCOLB122	10099902	LCOLB122	10109267	LCOLB122	10109543	LCOLB122	10109563
LCOLB122	10099904	LCOLB122	10109273	LCOLB122	10109544	LCOLB122	10109572
LESOP5P	10089409	LESOP5P	10089414	LESOP5P	10101793	LESOP5P	10101803

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LESOP8	10114328	LESOP8	10114313	LESOP8	10114322	LESOP8	10114338
LGBP293P	10091952	LGBP293P	10116238	LGBP293P	10110896	LGBP293P	10116245
LGBP293P	10091954	LGBP293P	10120104	LGBP293P	10110899	LGBP293P	10116247
LGBP293P	10092017	LGBP293P	10120112	LGBP293P	10110930	LGBP293P	10116248
LGBP293P	10092036	LGBP293P	10101417	LGBP293P	10110937	LGBP293P	10116253
LGBP293P	10092055	LGBP293P	10101412	LGBP293P	10110943	LGBP293P	10116260
LGBP293P	10092081	LGBP293P	10101414	LGBP293P	10110949	LGBP293P	10116265
LGBP293P	10094875	LGBP293P	10101416	LGBP293P	10110976	LGBP293P	10116266
LGBP293P	10094880	LGBP293P	10101421	LGBP293P	10110978	LGBP293P	10116282
LGBP293P	10094886	LGBP293P	10101422	LGBP293P	10110979	LGBP293P	10119885
LGBP293P	10094887	LGBP293P	10101426	LGBP293P	10110991	LGBP293P	10119891
LGBP293P	10094888	LGBP293P	10101428	LGBP293P	10110994	LGBP293P	10119895
LGBP293P	10094890	LGBP293P	10101434	LGBP293P	10111002	LGBP293P	10119900
LGBP293P	10094892	LGBP293P	10101436	LGBP293P	10111005	LGBP293P	10119923
LGBP293P	10094894	LGBP293P	10101445	LGBP293P	10111011	LGBP293P	10119932
LGBP293P	10094897	LGBP293P	10101446	LGBP293P	10111014	LGBP293P	10119935
LGBP293P	10094899	LGBP293P	10101449	LGBP293P	10111016	LGBP293P	10119939
LGBP293P	10094902	LGBP293P	10101450	LGBP293P	10111020	LGBP293P	10119945
LGBP293P	10094907	LGBP293P	10101453	LGBP293P	10111023	LGBP293P	10119950
LGBP293P	10094911	LGBP293P	10101455	LGBP293P	10111027	LGBP293P	10119954
LGBP293P	10094915	LGBP293P	10101459	LGBP293P	10111031	LGBP293P	10119968
LGBP293P	10094917	LGBP293P	10101460	LGBP293P	10111036	LGBP293P	10119972
LGBP293P	10094932	LGBP293P	10101470	LGBP293P	10113536	LGBP293P	10119980
LGBP293P	10094935	LGBP293P	10101495	LGBP293P	10113684	LGBP293P	10119984
LGBP293P	10094939	LGBP293P	10101516	LGBP293P	10090118	LGBP293P	10119990
LGBP293P	10094940	LGBP293P	10101517	LGBP293P	10090131	LGBP293P	10120056
LGBP293P	10094943	LGBP293P	10101518	LGBP293P	10090144	LGBP293P	10120062
LGBP293P	10094951	LGBP293P	10101522	LGBP293P	10090155	LGBP293P	10120071
LGBP293P	10094960	LGBP293P	10105880	LGBP293P	10090173	LGBP293P	10120079
LGBP293P	10094968	LGBP293P	10105885	LGBP293P	10090183	LGBP293P	10120086
LGBP293P	10094975	LGBP293P	10105889	LGBP293P	10090190	LGBP293P	10120117
LGBP293P	10103746	LGBP293P	10105905	LGBP293P	10090210	LGBP293P	10119902
LGBP293P	10103750	LGBP293P	10105914	LGBP293P	10090216	LGBP293P	10119905
LGBP293P	10103754	LGBP293P	10105920	LGBP293P	10090217	LGBP293P	10119906
LGBP293P	10103755	LGBP293P	10105924	LGBP293P	10090222	LGBP293P	10119908
LGBP293P	10103761	LGBP293P	10105965	LGBP293P	10090225	LGBP293P	10119909
LGBP293P	10103763	LGBP293P	10105903	LGBP293P	10090227	LGBP293P	10119915
LGBP293P	10103765	LGBP293P	10105930	LGBP293P	10090243	LGBP293P	10119916

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP293P	10103771	LGBP293P	10105940	LGBP293P	10090245	LGBP293P	10119919
LGBP293P	10103772	LGBP293P	10105948	LGBP293P	10090248	LGBP293P	10123158
LGBP293P	10103777	LGBP293P	10105961	LGBP293P	10090250	LGBP293P	10123161
LGBP293P	10103781	LGBP293P	10105972	LGBP293P	10090251	LGBP293P	10123165
LGBP293P	10103791	LGBP293P	10105974	LGBP293P	10090253	LGBP293P	10123173
LGBP293P	10103792	LGBP293P	10105978	LGBP293P	10090254	LGBP293P	10123177
LGBP293P	10103795	LGBP293P	10105968	LGBP293P	10090255	LGBP293P	10123178
LGBP293P	10103796	LGBP293P	10105982	LGBP293P	10090256	LGBP293P	10123189
LGBP293P	10103805	LGBP293P	10105997	LGBP293P	10090260	LGBP293P	10123190
LGBP293P	10103810	LGBP293P	10106050	LGBP293P	10090265	LGBP293P	10123197
LGBP293P	10103814	LGBP293P	10106064	LGBP293P	10091859	LGBP293P	10123200
LGBP293P	10103818	LGBP293P	10106086	LGBP293P	10091873	LGBP293P	10123202
LGBP293P	10103820	LGBP293P	10106100	LGBP293P	10091875	LGBP293P	10123203
LGBP293P	10103821	LGBP293P	10106107	LGBP293P	10091877	LGBP293P	10123207
LGBP293P	10103870	LGBP293P	10108127	LGBP293P	10091882	LGBP293P	10123211
LGBP293P	10103874	LGBP293P	10108146	LGBP293P	10091889	LGBP293P	10123219
LGBP293P	10103879	LGBP293P	10108158	LGBP293P	10091895	LGBP293P	10123224
LGBP293P	10113513	LGBP293P	10108164	LGBP293P	10091897	LGBP293P	10125739
LGBP293P	10113521	LGBP293P	10108169	LGBP293P	10091900	LGBP293P	10125741
LGBP293P	10113524	LGBP293P	10108170	LGBP293P	10091907	LGBP293P	10125778
LGBP293P	10113528	LGBP293P	10108172	LGBP293P	10091908	LGBP293P	10125784
LGBP293P	10113532	LGBP293P	10108173	LGBP293P	10091910	LGBP293P	10125786
LGBP293P	10113533	LGBP293P	10108175	LGBP293P	10091911	LGBP293P	10125789
LGBP293P	10113534	LGBP293P	10108176	LGBP293P	10091914	LGBP293P	10125791
LGBP293P	10113537	LGBP293P	10108178	LGBP293P	10091923	LGBP293P	10125793
LGBP293P	10113539	LGBP293P	10108179	LGBP293P	10091936	LGBP293P	10125797
LGBP293P	10113547	LGBP293P	10108180	LGBP293P	10091942	LGBP293P	10125798
LGBP293P	10113550	LGBP293P	10108182	LGBP293P	10091943	LGBP293P	10125801
LGBP293P	10113566	LGBP293P	10108186	LGBP293P	10116184	LGBP293P	10125805
LGBP293P	10113595	LGBP293P	10108188	LGBP293P	10116203	LGBP293P	10125806
LGBP293P	10113603	LGBP293P	10108177	LGBP293P	10116212	LGBP293P	10125809
LGBP293P	10113622	LGBP293P	10108183	LGBP293P	10116217	LGBP293P	10125811
LGBP293P	10113639	LGBP293P	10108184	LGBP293P	10116221	LGBP293P	10125813
LGBP293P	10113659	LGBP293P	10108193	LGBP293P	10116228	LGBP293P	10125818
LGBP293P	10113676	LGBP293P	10108192	LGBP293P	10116230	LGBP293P	10125825
LGBP293P	10113688	LGBP293P	10108194	LGBP293P	10116233	LGBP293P	10125829
LGBP293P	10113698	LGBP293P	10108200	LGBP293P	10116234	LGBP293P	10125839
LGBP293P	10113710	LGBP293P	10108216	LGBP293P	10116239	LGBP293P	10125888

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP293P	10113719	LGBP293P	10110889	LGBP293P	10116240	LGBP293P	10125911
LGBP293P	10116225	LGBP293P	10110891	LGBP293P	10116241	LGBP293P	10125919
LGBP293P	10116231	LGBP293P	10110893	LGBP293P	10116243	LGBP293P	10125927
LGBP296P	10097369	LGBP296P	10101014	LGBP296P	10110578	LGBP296P	10119125
LGBP296P	10097414	LGBP296P	10101026	LGBP296P	10110584	LGBP296P	10119127
LGBP296P	10097422	LGBP296P	10101027	LGBP296P	10110590	LGBP296P	10119128
LGBP296P	10097423	LGBP296P	10101030	LGBP296P	10110594	LGBP296P	10119130
LGBP296P	10102256	LGBP296P	10101032	LGBP296P	10117007	LGBP296P	10125959
LGBP296P	10102275	LGBP296P	10101033	LGBP296P	10117018	LGBP296P	10125981
LGBP296P	10102286	LGBP296P	10101034	LGBP296P	10117044	LGBP296P	10125986
LGBP296P	10102292	LGBP296P	10101035	LGBP296P	10117055	LGBP296P	10126004
LGBP296P	10114223	LGBP296P	10108856	LGBP296P	10119115	LGBP296P	10129801
LGBP296P	10114227	LGBP296P	10108868	LGBP296P	10119119	LGBP296P	10129808
LGBP296P	10114232	LGBP296P	10108874	LGBP296P	10119121	LGBP296P	10129819
LGBP296P	10114237	LGBP296P	10108878	LGBP296P	10119123	LGBP296P	10129825
LGBP394P	10092810	LGBP394P	10099158	LGBP394P	10109964	LGBP394P	10116004
LGBP394P	10092817	LGBP394P	10099163	LGBP394P	10109983	LGBP394P	10116014
LGBP394P	10092827	LGBP394P	10099169	LGBP394P	10109999	LGBP394P	10116023
LGBP394P	10092833	LGBP394P	10099176	LGBP394P	10110007	LGBP394P	10117431
LGBP394P	10095083	LGBP394P	10113324	LGBP394P	10111326	LGBP394P	10117442
LGBP394P	10095089	LGBP394P	10113335	LGBP394P	10111336	LGBP394P	10117447
LGBP394P	10095094	LGBP394P	10113345	LGBP394P	10111344	LGBP394P	10117451
LGBP394P	10095110	LGBP394P	10104891	LGBP394P	10111350	LGBP394P	10123542
LGBP394P	10096806	LGBP394P	10104901	LGBP394P	10113313	LGBP394P	10123564
LGBP394P	10096810	LGBP394P	10104909	LGBP394P	10091455	LGBP394P	10123570
LGBP394P	10096813	LGBP394P	10104917	LGBP394P	10114597	LGBP394P	10123577
LGBP394P	10096818	LGBP394P	10107322	LGBP394P	10114600	LGBP394P	10127099
LGBP394P	10097935	LGBP394P	10107383	LGBP394P	10114604	LGBP394P	10127105
LGBP394P	10097941	LGBP394P	10107400	LGBP394P	10114609	LGBP394P	10127112
LGBP394P	10097948	LGBP394P	10107416	LGBP394P	10115995	LGBP394P	10127143
LGBP394P	10097963	LGBP394P	-	LGBP394P	-	LGBP394P	-
LGBP478P	10097344	LGBP478P	10106368	LGBP478P	10109277	LGBP478P	10091527
LGBP478P	10097353	LGBP478P	10106370	LGBP478P	10109283	LGBP478P	10091534
LGBP478P	10097362	LGBP478P	10106378	LGBP478P	10109290	LGBP478P	10119936
LGBP478P	10097425	LGBP478P	10106380	LGBP478P	10111317	LGBP478P	10119947
LGBP478P	10121088	LGBP478P	10106384	LGBP478P	10111319	LGBP478P	10119970
LGBP478P	10099395	LGBP478P	10106387	LGBP478P	10111323	LGBP478P	10119973
LGBP478P	10099398	LGBP478P	10106394	LGBP478P	10111325	LGBP478P	10121097

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP478P	10099405	LGBP478P	10106401	LGBP478P	10111442	LGBP478P	10121104
LGBP478P	10099409	LGBP478P	10108313	LGBP478P	10111446	LGBP478P	10121114
LGBP478P	10099414	LGBP478P	10108315	LGBP478P	10111450	LGBP478P	10124547
LGBP478P	10099422	LGBP478P	10108319	LGBP478P	10111453	LGBP478P	10124557
LGBP478P	10099429	LGBP478P	10108322	LGBP478P	10091506	LGBP478P	10124560
LGBP478P	10099440	LGBP478P	10109258	LGBP478P	10091522	LGBP478P	10124563
LGBP488	10092480	LGBP488	10092535	LGBP488	10099879	LGBP488	10099891
LGBP488	10092465	LGBP488	10092558	LGBP488	10099884	LGBP488	10099907
LGBP510	10098556	LGBP510	10108562	LGBP510	10124036	LGBP510	10123866
LGBP510	10101616	LGBP510	10108571	LGBP510	10124042	LGBP510	10123869
LGBP510	10101695	LGBP510	10108573	LGBP510	10124052	LGBP510	10123870
LGBP510	10101708	LGBP510	10090822	LGBP510	10124056	LGBP510	10123873
LGBP510	10101712	LGBP510	10090827	LGBP510	10128334	LGBP510	10123876
LGBP510	10116460	LGBP510	10090846	LGBP510	10128338	LGBP510	10123877
LGBP510	10098525	LGBP510	10090925	LGBP510	10128342	LGBP510	10123880
LGBP510	10098546	LGBP510	10116426	LGBP510	10128345	LGBP510	10123882
LGBP510	10098550	LGBP510	10116441	LGBP510	10123860	LGBP510	10123883
LGBP510	10108558	LGBP510	10116453	LGBP510	10123863	LGBP510	10123885
LGBP510P	10092857	LGBP510P	10099877	LGBP510P	10109602	LGBP510P	10117874
LGBP510P	10092861	LGBP510P	10100133	LGBP510P	10109607	LGBP510P	10117895
LGBP510P	10092880	LGBP510P	10100138	LGBP510P	10110186	LGBP510P	10117602
LGBP510P	10092953	LGBP510P	10100144	LGBP510P	10110204	LGBP510P	10117615
LGBP510P	10092962	LGBP510P	10100149	LGBP510P	10110213	LGBP510P	10117634
LGBP510P	10092974	LGBP510P	10100385	LGBP510P	10110220	LGBP510P	10117662
LGBP510P	10092980	LGBP510P	10100394	LGBP510P	10112409	LGBP510P	10118202
LGBP510P	10092987	LGBP510P	10100398	LGBP510P	10112415	LGBP510P	10118292
LGBP510P	10093676	LGBP510P	10100400	LGBP510P	10112416	LGBP510P	10118296
LGBP510P	10093683	LGBP510P	10104925	LGBP510P	10112418	LGBP510P	10118309
LGBP510P	10093688	LGBP510P	10104927	LGBP510P	10112671	LGBP510P	10118310
LGBP510P	10093697	LGBP510P	10104941	LGBP510P	10112691	LGBP510P	10118313
LGBP510P	10095035	LGBP510P	10104956	LGBP510P	10112705	LGBP510P	10118320
LGBP510P	10095041	LGBP510P	10105988	LGBP510P	10112711	LGBP510P	10118338
LGBP510P	10095046	LGBP510P	10105996	LGBP510P	10114320	LGBP510P	10118141
LGBP510P	10095054	LGBP510P	10106005	LGBP510P	10114329	LGBP510P	10118149
LGBP510P	10098369	LGBP510P	10106010	LGBP510P	10114332	LGBP510P	10118157
LGBP510P	10098377	LGBP510P	10106864	LGBP510P	10114333	LGBP510P	10118166
LGBP510P	10098390	LGBP510P	10106868	LGBP510P	10114583	LGBP510P	10118899
LGBP510P	10098396	LGBP510P	10106876	LGBP510P	10088794	LGBP510P	10118907

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP510P	10098498	LGBP510P	10106882	LGBP510P	10088815	LGBP510P	10118911
LGBP510P	10098500	LGBP510P	10107949	LGBP510P	10088973	LGBP510P	10118913
LGBP510P	10102855	LGBP510P	10107963	LGBP510P	10088982	LGBP510P	10125217
LGBP510P	10102914	LGBP510P	10107975	LGBP510P	10088996	LGBP510P	10125224
LGBP510P	10102918	LGBP510P	10107987	LGBP510P	10089006	LGBP510P	10125229
LGBP510P	10102924	LGBP510P	10108936	LGBP510P	10091198	LGBP510P	10125231
LGBP510P	10095989	LGBP510P	10108947	LGBP510P	10091206	LGBP510P	10126448
LGBP510P	10096000	LGBP510P	10108955	LGBP510P	10091213	LGBP510P	10126485
LGBP510P	10096028	LGBP510P	10108961	LGBP510P	10091221	LGBP510P	10126494
LGBP510P	10096036	LGBP510P	10109282	LGBP510P	10114603	LGBP510P	10126505
LGBP510P	10098502	LGBP510P	10109292	LGBP510P	10114605	LGBP510P	10129359
LGBP510P	10098504	LGBP510P	10109314	LGBP510P	10114613	LGBP510P	10129365
LGBP510P	10099858	LGBP510P	10109331	LGBP510P	10117835	LGBP510P	10129366
LGBP510P	10099866	LGBP510P	10109585	LGBP510P	10117848	LGBP510P	10129372
LGBP510P	10099873	LGBP510P	10109592	LGBP510P	-	LGBP510P	
LGBP510R	10121518	LGBP510R	10123308	LGBP510R	10125133	LGBP510R	10126257
LGBP510R	10121534	LGBP510R	10123315	LGBP510R	10125142	LGBP510R	10126266
LGBP510R	10121540	LGBP510R	10123703	LGBP510R	10125154	LGBP510R	10127037
LGBP510R	10121548	LGBP510R	10123713	LGBP510R	10125168	LGBP510R	10127054
LGBP510R	10123266	LGBP510R	10123720	LGBP510R	10126243	LGBP510R	10127061
LGBP510R	10123286	LGBP510R	10123727	LGBP510R	10126249	LGBP510R	10127084
LGBP515	10095051	LGBP515	10103914	LGBP515	10099693	LGBP515	10108490
LGBP515	10095064	LGBP515	10103919	LGBP515	10099700	LGBP515	10108485
LGBP515	10095119	LGBP515	10103924	LGBP515	10099775	LGBP515	10108496
LGBP515	10095123	LGBP515	10103926	LGBP515	10099779	LGBP515	10108500
LGBP515	10095124	LGBP515	10103928	LGBP515	10099785	LGBP515	10108504
LGBP515	10095128	LGBP515	10103931	LGBP515	10108459	LGBP515	10091412
LGBP515	10099683	LGBP515	10103933	LGBP515	10108468	LGBP515	10091416
LGBP515	10099706	LGBP515	10099688	LGBP515	10108482	LGBP515	10091417
LGBP515	10103909	LGBP515	-	LGBP515	-	LGBP515	-
LGBP516P	10093671	LGBP516P	10095075	LGBP516P	10107993	LGBP516P	10089370
LGBP516P	10093682	LGBP516P	10095082	LGBP516P	10108004	LGBP516P	10126372
LGBP516P	10093711	LGBP516P	10095085	LGBP516P	10089292	LGBP516P	10126382
LGBP516P	10093757	LGBP516P	10107938	LGBP516P	10089293	LGBP516P	10126389
LGBP516P	10095033	LGBP516P	10107945	LGBP516P	10089297	LGBP516P	10126393
LGBP516P	10095036	LGBP516P	10107951	LGBP516P	10089312	LGBP516P	10126400
LGBP516P	10095039	LGBP516P	10107957	LGBP516P	10089326	LGBP516P	10126463
LGBP516P	10095043	LGBP516P	10107972	LGBP516P	10089339	LGBP516P	10126471

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP516P	10095048	LGBP516P	10107983	LGBP516P	10089354	LGBP516P	10126484
LGBP550P	10101869	LGBP550P	10101890	LGBP550P	10103863	LGBP550P	10089714
LGBP550P	10101881	LGBP550P	10103854	LGBP550P	10103883	LGBP550P	10089717
LGBP550P	10101882	LGBP550P	10103861	LGBP550P	10089706	LGBP550P	10089722
LGBP550R	10121565	LGBP550R	10121597	LGBP550R	10126311	LGBP550R	10126323
LGBP550R	10121588	LGBP550R	10121609	LGBP550R	10126316	LGBP550R	10126328
LGBP557	10109473	LGBP557	10109515	LGBP557	10115391	LGBP557	10125125
LGBP557	10109477	LGBP557	10115377	LGBP557	10115414	LGBP557	10125129
LGBP557	10109479	LGBP557	10115385	LGBP557	10125121	LGBP557	10125131
LGBP558	10092330	LGBP558	10102651	LGBP558	10109484	LGBP558	10118088
LGBP558	10092337	LGBP558	10099724	LGBP558	10109489	LGBP558	10121099
LGBP558	10092342	LGBP558	10099727	LGBP558	10112611	LGBP558	10121105
LGBP558	10092345	LGBP558	10100755	LGBP558	10112617	LGBP558	10121109
LGBP558	10094645	LGBP558	10100760	LGBP558	10112621	LGBP558	10121115
LGBP558	10094665	LGBP558	10100763	LGBP558	10112626	LGBP558	10121896
LGBP558	10094669	LGBP558	10100768	LGBP558	10115604	LGBP558	10121902
LGBP558	10094672	LGBP558	10101295	LGBP558	10115611	LGBP558	10121909
LGBP558	10098516	LGBP558	10101296	LGBP558	10115615	LGBP558	10121918
LGBP558	10098521	LGBP558	10101301	LGBP558	10115643	LGBP558	10124142
LGBP558	10098528	LGBP558	10101349	LGBP558	10115637	LGBP558	10124150
LGBP558	10098531	LGBP558	10105981	LGBP558	10115655	LGBP558	10124156
LGBP558	10099699	LGBP558	10105993	LGBP558	10115665	LGBP558	10124162
LGBP558	10099721	LGBP558	10106003	LGBP558	10115672	LGBP558	10128712
LGBP558	10102629	LGBP558	10106009	LGBP558	10116297	LGBP558	10128718
LGBP558	10102637	LGBP558	10109448	LGBP558	10118080	LGBP558	10128730
LGBP558	10102645	LGBP558	10109452	LGBP558	10118083	LGBP558	10128748
LGBP591	10092620	LGBP591	10099032	LGBP591	10111262	LGBP591	10118989
LGBP591	10092624	LGBP591	10099108	LGBP591	10111289	LGBP591	10118997
LGBP591	10092628	LGBP591	10099118	LGBP591	10111292	LGBP591	10119000
LGBP591	10092635	LGBP591	10099239	LGBP591	10111293	LGBP591	10119003
LGBP591	10093086	LGBP591	10099248	LGBP591	10111296	LGBP591	10119006
LGBP591	10093091	LGBP591	10099715	LGBP591	10111516	LGBP591	10119018
LGBP591	10093094	LGBP591	10099720	LGBP591	10111517	LGBP591	10119027
LGBP591	10093105	LGBP591	10099725	LGBP591	10111518	LGBP591	10119037
LGBP591	10093090	LGBP591	10099726	LGBP591	10111522	LGBP591	10119014
LGBP591	10093097	LGBP591	10099728	LGBP591	10111523	LGBP591	10119022
LGBP591	10093111	LGBP591	10099732	LGBP591	10111525	LGBP591	10119041
LGBP591	10093132	LGBP591	10099733	LGBP591	10111528	LGBP591	10119044

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP591	10093618	LGBP591	10099735	LGBP591	10111530	LGBP591	10119047
LGBP591	10093622	LGBP591	10100520	LGBP591	10112008	LGBP591	10119052
LGBP591	10093627	LGBP591	10100523	LGBP591	10112012	LGBP591	10119066
LGBP591	10093634	LGBP591	10100535	LGBP591	10112014	LGBP591	10119067
LGBP591	10094912	LGBP591	10100540	LGBP591	10112045	LGBP591	10119070
LGBP591	10094919	LGBP591	10100539	LGBP591	10112048	LGBP591	10119071
LGBP591	10094920	LGBP591	10100543	LGBP591	10112049	LGBP591	10119073
LGBP591	10094922	LGBP591	10100550	LGBP591	10112050	LGBP591	10119082
LGBP591	10094923	LGBP591	10100555	LGBP591	10112054	LGBP591	10119097
LGBP591	10094926	LGBP591	10100982	LGBP591	10113041	LGBP591	10119103
LGBP591	10094929	LGBP591	10100985	LGBP591	10113054	LGBP591	10119108
LGBP591	10094934	LGBP591	10100988	LGBP591	10113075	LGBP591	10119111
LGBP591	10095291	LGBP591	10100991	LGBP591	10113079	LGBP591	10121348
LGBP591	10095294	LGBP591	10100995	LGBP591	10113094	LGBP591	10121224
LGBP591	10095312	LGBP591	10101001	LGBP591	10113100	LGBP591	10121228
LGBP591	10095314	LGBP591	10101003	LGBP591	10113102	LGBP591	10121232
LGBP591	10095319	LGBP591	10101004	LGBP591	10113106	LGBP591	10121237
LGBP591	10095323	LGBP591	10104080	LGBP591	10088893	LGBP591	10121241
LGBP591	10095379	LGBP591	10104085	LGBP591	10088899	LGBP591	10121296
LGBP591	10099044	LGBP591	10104090	LGBP591	10088911	LGBP591	10121313
LGBP591	10099048	LGBP591	10104093	LGBP591	10088924	LGBP591	10123235
LGBP591	10099055	LGBP591	10104094	LGBP591	10089197	LGBP591	10123240
LGBP591	10099062	LGBP591	10104099	LGBP591	10089199	LGBP591	10123249
LGBP591	10099068	LGBP591	10104103	LGBP591	10089202	LGBP591	10123256
LGBP591	10099211	LGBP591	10104104	LGBP591	10089206	LGBP591	10123261
LGBP591	10099215	LGBP591	10104517	LGBP591	10089262	LGBP591	10123267
LGBP591	10099220	LGBP591	10104524	LGBP591	10089263	LGBP591	10123274
LGBP591	10099223	LGBP591	10104530	LGBP591	10089266	LGBP591	10123284
LGBP591	10099227	LGBP591	10104535	LGBP591	10089267	LGBP591	10124479
LGBP591	10099258	LGBP591	10104539	LGBP591	10089270	LGBP591	10124481
LGBP591	10102222	LGBP591	10104566	LGBP591	10089272	LGBP591	10124482
LGBP591	10102230	LGBP591	10104577	LGBP591	10089273	LGBP591	10124485
LGBP591	10102231	LGBP591	10104585	LGBP591	10089274	LGBP591	10124575
LGBP591	10102233	LGBP591	10104863	LGBP591	10089287	LGBP591	10124579
LGBP591	10102235	LGBP591	10104870	LGBP591	10089289	LGBP591	10124584
LGBP591	10102248	LGBP591	10104878	LGBP591	10089291	LGBP591	10124588
LGBP591	10102253	LGBP591	10104884	LGBP591	10089522	LGBP591	10126735
LGBP591	10102259	LGBP591	10104894	LGBP591	10091279	LGBP591	10126743

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP591	10102606	LGBP591	10104910	LGBP591	10091282	LGBP591	10126744
LGBP591	10102616	LGBP591	10104924	LGBP591	10091285	LGBP591	10126748
LGBP591	10102625	LGBP591	10104931	LGBP591	10091288	LGBP591	10126749
LGBP591	10102630	LGBP591	10107769	LGBP591	10114821	LGBP591	10126752
LGBP591	10102633	LGBP591	10107780	LGBP591	10114827	LGBP591	10126756
LGBP591	10102636	LGBP591	10107786	LGBP591	10114832	LGBP591	10126761
LGBP591	10102641	LGBP591	10107788	LGBP591	10114843	LGBP591	10126898
LGBP591	10102770	LGBP591	10107795	LGBP591	10114849	LGBP591	10126900
LGBP591	10103127	LGBP591	10107800	LGBP591	10115131	LGBP591	10126907
LGBP591	10103129	LGBP591	10107802	LGBP591	10115135	LGBP591	10126911
LGBP591	10103131	LGBP591	10107892	LGBP591	10115139	LGBP591	10126913
LGBP591	10103136	LGBP591	10108273	LGBP591	10115147	LGBP591	10126918
LGBP591	10103139	LGBP591	10108281	LGBP591	10115151	LGBP591	10126921
LGBP591	10103141	LGBP591	10108289	LGBP591	10115154	LGBP591	10126925
LGBP591	10103148	LGBP591	10108296	LGBP591	10115161	LGBP591	10128109
LGBP591	10103158	LGBP591	10108297	LGBP591	10115165	LGBP591	10128110
LGBP591	10113648	LGBP591	10108308	LGBP591	10116456	LGBP591	10128112
LGBP591	10113656	LGBP591	10108312	LGBP591	10116464	LGBP591	10128113
LGBP591	10113666	LGBP591	10108316	LGBP591	10116468	LGBP591	10128178
LGBP591	10113704	LGBP591	10108666	LGBP591	10116474	LGBP591	10128185
LGBP591	10113707	LGBP591	10108673	LGBP591	10116477	LGBP591	10128192
LGBP591	10113713	LGBP591	10108677	LGBP591	10116482	LGBP591	10128196
LGBP591	10113722	LGBP591	10108685	LGBP591	10117424	LGBP591	10128418
LGBP591	10113728	LGBP591	10108693	LGBP591	10117428	LGBP591	10128426
LGBP591	10114802	LGBP591	10108700	LGBP591	10117433	LGBP591	10128434
LGBP591	10114811	LGBP591	10108708	LGBP591	10117453	LGBP591	10128441
LGBP591	10114816	LGBP591	10108714	LGBP591	10117455	LGBP591	10128454
LGBP591	10116445	LGBP591	10110421	LGBP591	10117462	LGBP591	10128462
LGBP591	10116452	LGBP591	10110433	LGBP591	10117480	LGBP591	10128466
LGBP591	10095446	LGBP591	10110441	LGBP591	10117486	LGBP591	10128473
LGBP591	10095592	LGBP591	10110450	LGBP591	10118046	LGBP591	10128989
LGBP591	10095595	LGBP591	10110453	LGBP591	10118050	LGBP591	10128990
LGBP591	10095596	LGBP591	10110459	LGBP591	10118067	LGBP591	10128993
LGBP591	10095598	LGBP591	10110463	LGBP591	10118077	LGBP591	10128996
LGBP591	10095601	LGBP591	10110472	LGBP591	10118078	LGBP591	10128998
LGBP591	10095603	LGBP591	10111215	LGBP591	10118084	LGBP591	10129002
LGBP591	10095612	LGBP591	10111219	LGBP591	10118085	LGBP591	10129006
LGBP591	10095617	LGBP591	10111222	LGBP591	10118091	LGBP591	10129009

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP636	10103561	LGBP636	10111540	LGBP636	10123075	LGBP636	10125572
LGBP636	10103569	LGBP636	10111644	LGBP636	10123078	LGBP636	10128547
LGBP636	10103577	LGBP636	10111650	LGBP636	10123774	LGBP636	10128556
LGBP636	10103583	LGBP636	10117571	LGBP636	10123786	LGBP636	10128569
LGBP636	10105033	LGBP636	10117579	LGBP636	10123794	LGBP636	10128577
LGBP636	10105041	LGBP636	10117585	LGBP636	10123797	LGBP636	10128957
LGBP636	10105046	LGBP636	10117591	LGBP636	10125500	LGBP636	10128963
LGBP636	10105050	LGBP636	10123061	LGBP636	10125549	LGBP636	10128964
LGBP636	10111532	LGBP636	10123074	LGBP636	10125563	LGBP636	10128965
LGBP637	10100674	LGBP637	10100676	LGBP637	10100680	LGBP637	10100683
LGBP649	10121310	LGBP649	10121321	LGBP649	10128507	LGBP649	10128531
LGBP649	10121311	LGBP649	10121335	LGBP649	10128518	LGBP649	10128539
LSRB12	10123313	LSRB12	10123358	LSRB12	10124614	LSRB12	10129421
LSRB12	10123323	LSRB12	10124565	LSRB12	10125353	LSRB12	10129429
LSRB12	10123328	LSRB12	10124613	LSRB12	10125519	LSRB12	-

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

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

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 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 **[Insert Affiliate Information]** 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 7, to receive replacement product/credit and place a replacement/credit note order. **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 product, and affix the pre-paid authorized shipping label included with the Field Safety Notice. Ethicon will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by calling **[Insert Affiliate Information]**. Your account number and mailing address have been pre-populated on the BRF.
7. If you are returning impacted product in your inventory, please contact us for replacement/credit and return the product to **[Insert Affiliate Information]**. If you require any assistance with returning product, please contact **[Insert Affiliate Information]**.

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.

If you have additional questions regarding this Field Safety Corrective Action or to report any customer complaints, please contact **[INSERT AFFILIATE INFORMATION]**.

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

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

communications, please contact your local Sales Representative.

ATTACHMENTS:

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form (BRF)

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

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)

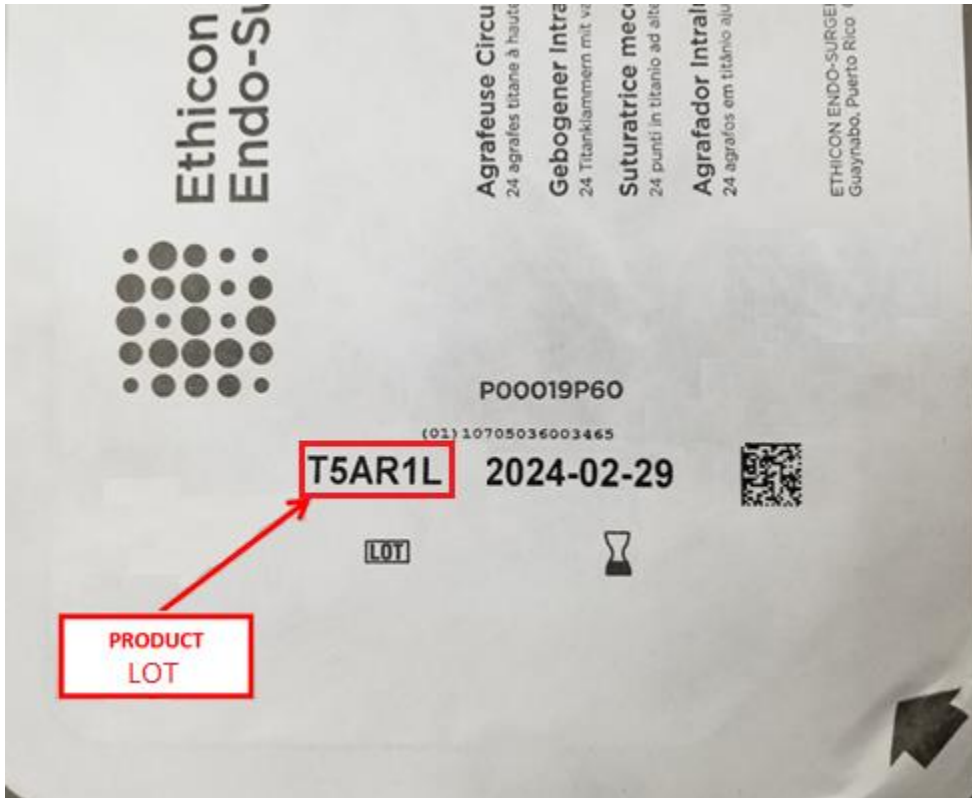
FRONT OF SINGLE UNIT CARTON



URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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



URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and fax this form to [INSERT AFFILIATE NAME] at [INSERT FAX NUMBER] at or e-mail the form to [INSERT AFFILIATE EMAIL ADDRESS] within 3 business days, even if you do not have product subject to this Field Safety Corrective Action to return.

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	PRODUCT CODE	LOT Number	Quantity Returning (Eaches)
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (21mm)	CDH21A CDH21AU		
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (25mm)	CDH25A CDH25AU		
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (29mm)	CDH29A CDH29AU		
Ethicon Endo-Surgery Curved Intraluminal Staplers (ILS) (33mm)	CDH33A CDH33AU		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (21mm)	ECS21A		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (25mm)	ECS25A ECS25AU		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (29mm)	ECS29A ECS29AU		
Ethicon Endo-Surgery Endoscopic Curved Intraluminal Staplers (ILS) (33mm)	ECS33A ECS33AU		

URGENT: FIELD SAFETY NOTICE

Intraluminal Stapler (ILS)

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

Kit Code	Kit Lot Number	Quantity Returning (Box)

[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*: <small>*Your signature provides confirmation that you have received and understood this notification</small>	
Your comments are welcome.	