

URGENT: FIELD SAFETY NOTICE
HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS
+ ADAPTIVE TISSUE TECHNOLOGY
(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)
(Specific Lots of Codes HAR23 and HAR36) – Voluntary Product Recall

May XX, 2018

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

PLEASE DISTRIBUTE THIS INFORMATION WITHIN YOUR FACILITY TO ALL PERSONNEL RESPONSIBLE FOR HARMONIC ACE®+ Shears with Adaptive Tissue Technology (23CM and 36CM LENGTHS)

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 voluntary medical device recall (removal) of specific lots of **HARMONIC ACE®+ Shears with Adaptive Tissue Technology (23CM and 36CM)**, as listed in the table above. Through Post-Market Surveillance efforts and per conducted investigation, Ethicon confirmed that some devices contained in these lots may have been assembled with an internal component that may cause continuous or inadvertent activation of the device. **For that reason, we are issuing this recall for the above listed product lots.**

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS BELONGING TO HARMONIC ACE®+ Shears with Adaptive Tissue Technology (ONLY SPECIFIC LOTS BELOW). REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS:

Table1. HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS + ADAPTIVE TISSUE TECHNOLOGY Product Codes

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS	
HARMONIC ACE®+ Shears with Adaptive Tissue Technology (23CM Length)	HAR23	P93T5J	P9409V
		P93T5K	P94A93
		P93V06	P94A94
		P93W4Y	P94C8R
		P93Y4A	P94G1W

URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)
HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS
+ ADAPTIVE TISSUE TECHNOLOGY
(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)
(Specific Lots of Codes HAR23 and HAR36)

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS			
HARMONIC ACE®+ Shears with Adaptive Tissue Technology (36CM Length)	HAR36	N9392K	P9396C	P93V0W	P94D9K
		N93978	P9399T	P93X2X	P94E1Z
		P9123A	P93A1L	P93X4E	P94E20
		P9129W	P93M0K	P93X85	P94E3Z
		P91301	P93M0L	P93X98	P94E8W
		P9144R	P93M5Y	P93Y48	P94F1M
		P9149J	P93N01	P93Y8X	P94F3A
		P9168K	P93N3Y	P93Z4T	P94F5T
		P9173R	P93N5A	P93Z5X	P94F6C
		P91795	P93P09	P93Z95	P94G1G
		P91C51	P93P26	P94015	P94G1J
		P91C83	P93R10	P9410Z	
		P91D30	P93R4F	P94A5K	
		P91K68	P93R4G	P94A6A	
		P91K69	P93R56	P94C5R	
		P91L0H	P93R6V	P94C8T	
		P91L0J	P93T0X	P94D3J	
		P91L1Y	P93T9L	P94D3K	
		P91L6J	P93U17	P94D5G	
		P9396A	P93V02	P94D7Z	

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
LCOL102	10028477	LGBP505	10033953	LSR158	10033106
LCOL102	10028479	LGBP505	10033959	LSR158	10033744
LCOL102	10028484	LGBP505	10033962	LSR158	10033752
LCOL102	10028488	LGBP505	10033963	LSR158	10033757
LCOL104	10033033	LGBP505	10033967	LSR158	10033762
LCOL104	10033039	LGBP505	10033968	LSR158	10034398
LCOL104	10033059	LGBP505	10033969	LSR158	10034403
LCOL104	10033066	LGBP505	10033970	LSR158	10034407
LCOL104	10036190	LGBP505	10035803	LSR158	10034410
LCOL104	10036229	LGBP505	10035809	LSR158	10035070
LCOL104	10036232	LGBP505	10035819	LSR158	10035089
LCOL104	10036236	LGBP505	10035828	LSR158	10035095
LCOL104	10069056	LGBP505	10035835	LSR158	10035100
LCOL104	10069059	LGBP505	10035838	LSR158	10035177
LCOL104	10069062	LGBP505	10035850	LSR158	10035178

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HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS

+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL104	10069065	LGBP505	10035851	LSR158	10035181
LCOL104	10070983	LGBP505	10035852	LSR158	10035184
LCOL104	10070994	LGBP505	10035859	LSR158	10035185
LCOL104	10071002	LGBP505	10035865	LSR158	10035187
LCOL104	10071008	LGBP505	10035868	LSR158	10035188
LCOL104	10075633	LGBP505	10055345	LSR158	10035202
LCOL104	10075654	LGBP505	10055388	LSR158	10036895
LCOL104	10075657	LGBP505	10055375	LSR158	10036903
LCOL104	10075662	LGBP505	10055377	LSR158	10036908
LCOL105	10032964	LGBP505	10055383	LSR158	10036936
LCOL105	10032967	LGBP505	10055395	LSR158	10055141
LCOL105	10032970	LGBP505	10055400	LSR158	10055149
LCOL105	10032975	LGBP505	10055404	LSR158	10055171
LCOL105	10034417	LGBP505	10055405	LSR158	10055187
LCOL105	10034422	LGBP505	10055406	LSR158	10061835
LCOL105	10034428	LGBP505	10055408	LSR158	10061845
LCOL105	10034431	LGBP505	10055412	LSR158	10068387
LCOL105	10036600	LGBP505	10074098	LSR158	10068391
LCOL105	10036606	LGBP505	10074103	LSR158	10068400
LCOL105	10036612	LGBP505	10074110	LSR158	10068406
LCOL105	10036616	LGBP505	10074111	LSR158	10069179
LCOL105	10056196	LGBP540	10030378	LSR158	10069187
LCOL105	10056202	LGBP540	10030380	LSR158	10069190
LCOL105	10056207	LGBP540	10032330	LSR158	10069194
LCOL105	10056233	LGBP540	10036919	LSR158	10069572
LCOL105	10061979	LGBP540	10036928	LSR158	10069576
LCOL105	10061991	LGBP540	10036940	LSR158	10069582
LCOL105	10061997	LGBP540	10036968	LSR158	10069616
LCOL105	10062005	LGBP540	10056007	LSR158	10069622
LCOL105	10062006	LGBP540	10056039	LSR158	10069625
LCOL105	10062011	LGBP540	10056013	LSR158	10069628
LCOL105	10066760	LGBP540	10056025	LSR158	10069630
LCOL105	10066778	LGBP540	10056034	LSR158	10073032
LCOL105	10066783	LGBP540	10056097	LSR158	10073038
LCOL105	10066858	LGBP540	10056062	LSR158	10073040
LCOL105	10069046	LGBP540	10056064	LSR158	10073047
LCOL105	10069057	LGBP540	10056066	LSR158	10074469
LCOL105	10071119	LGBP540	10056069	LSR158	10074477
LCOL105	10071132	LGBP540	10056073	LSR158	10074482
LCOL105	10071143	LGBP540	10056078	LSR158	10074491
LCOL105	10071153	LGBP540	10056082	LSR158	10074499
LCOL105	10074649	LGBP540	10056101	LSR158	10074510
LCOL105	10074657	LGBP540	10056103	LSR158	10074519
LCOL105	10074670	LGBP540	10056110	LSR158	10074539

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HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS

+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL105	10074678	LGBP540	10072180	LSR158	10075594
LCOL58	10033770	LGBP540	10072208	LSR158	10075604
LCOL58	10033799	LGBP540	10072214	LSR158	10075612
LCOL58	10033802	LGBP540	10072224	LSR158	10071593
LCOL58	10033804	LGBP540	10074334	LSR158	10071603
LCOL58	10033807	LGBP540	10074350	LSR158	10071613
LCOL58	10033810	LGBP540	10074375	LSR158	10071619
LCOL58	10033831	LGBP540	10074398	LSR162	10027932
LCOL58	10034437	LGBP542	10030135	LSR162	10027937
LCOL58	10034438	LGBP542	10030139	LSR162	10027943
LCOL58	10034442	LGBP542	10030143	LSR162	10027944
LCOL58	10034446	LGBP542	10030146	LSR162	10035012
LCOL58	10036007	LGBP542	10030148	LSR162	10035015
LCOL58	10036011	LGBP542	10030149	LSR162	10036766
LCOL58	10036015	LGBP542	10030153	LSR162	10036767
LCOL58	10036022	LGBP542	10030155	LSR162	10036774
LCOL58	10055097	LGBP542	10030156	LSR162	10036779
LCOL58	10055100	LGBP542	10030160	LSR185	10073171
LCOL58	10055102	LGBP542	10033988	LSR185	10073181
LCOL58	10055222	LGBP542	10034080	LSR185	10073184
LCOL58	10067557	LGBP542	10034084	LSR185	10073187
LCOL58	10067561	LGBP542	10034085	LSR190	10029655
LCOL58	10067564	LGBP542	10034088	LSR190	10029661
LCOL58	10067576	LGBP542	10034090	LSR190	10029663
LCOL58	10068143	LGBP542	10034284	LSR190	10029668
LCOL58	10068145	LGBP542	10034292	LSR190	10029670
LCOL58	10068147	LGBP542	10034365	LSR190	10029672
LCOL58	10068148	LGBP542	10034375	LSR190	10035211
LCOL58	10068152	LGBP542	10034414	LSR190	10035219
LCOL58	10068153	LGBP542	10034416	LSR190	10035224
LCOL58	10068154	LGBP542	10034418	LSR190	10035228
LCOL58	10068158	LGBP542	10034421	LSR190	10035253
LCOL58	10068159	LGBP542	10034423	LSR190	10035261
LCOL58	10068160	LGBP542	10034425	LSR190	10035265
LCOL58	10068187	LGBP542	10034427	LSR190	10035326
LCOL58	10068192	LGBP542	10034429	LSR190	10035336
LCOL58	10068901	LGBP542	10036677	LSR190	10035348
LCOL58	10068904	LGBP542	10036681	LSR190	10035354
LCOL58	10068907	LGBP542	10036682	LSR190	10035357
LCOL58	10068914	LGBP542	10036720	LSR190	10036776
LCOL58	10071164	LGBP542	10036724	LSR190	10036784
LCOL58	10072942	LGBP542	10036748	LSR190	10036785
LCOL58	10072944	LGBP542	10061981	LSR190	10036787
LCOL58	10072950	LGBP542	10061994	LSR190	10036789

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HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS

+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL58	10075676	LGBP542	10062017	LSR190	10036794
LCOL58	10075680	LGBP542	10062021	LSR190	10036796
LCOL58	10075699	LGBP542	10062024	LSR190	10036809
LCOL58	10075700	LGBP542	10062025	LSR200	10029824
LCOL58	10075714	LGBP542	10062030	LSR200	10029827
LCOL58	10075721	LGBP542	10062037	LSR200	10029828
LCOL58	10075723	LGBP542	10062039	LSR200	10029831
LCOL58	10075731	LGBP542	10062046	LSR200	10029833
LCOL58	10075738	LGBP542	10062054	LSR200	10029834
LCOL58	10075742	LGBP542	10062058	LSR200	10029837
LCOL58	10075744	LGBP542	10062500	LSR200	10029843
LCOL58	10075747	LGBP542	10062516	LSR200	10055135
LCOL71	10036836	LGBP542	10062520	LSR200	10055139
LCOL71	10036839	LGBP542	10062541	LSR200	10055144
LCOL71	10036844	LGBP542	10062559	LSR200	10055146
LCOL71	10036857	LGBP542	10062564	LSR200	10062308
LCOL71	10056452	LGBP542	10062565	LSR200	10062317
LCOL71	10056578	LGBP542	10062570	LSR200	10062322
LCOL71	10056589	LGBP542	10062579	LSR200	10062330
LCOL71	10056599	LGBP542	10062585	LSR200	10062371
LCOL71	10072963	LGBP542	10062588	LSR200	10062375
LCOL71	10072967	LGBP542	10062598	LSR200	10062381
LCOL71	10072970	LGBP542	10068732	LSR200	10062386
LCOL71	10072987	LGBP542	10068737	LSR200	10068079
LCOL71	10072992	LGBP542	10070116	LSR200	10068083
LCOL71	10073080	LGBP542	10070122	LSR200	10068085
LCOL71	10073086	LGBP542	10070126	LSR200	10068092
LCOL71	10073093	LGBP542	10070130	LSR200	10069085
LCOL72	10034253	LGBP542	10070135	LSR200	10069093
LCOL72	10034257	LGBP542	10070183	LSR200	10069106
LCOL72	10034260	LGBP542	10070192	LSR200	10069114
LCOL72	10034264	LGBP542	10070193	LSR200	10069188
LCOL86	10029542	LGBP542	10070211	LSR200	10069191
LCOL86	10073084	LGBP542	10070228	LSR200	10069197
LCOL86	10073173	LGBP542	10070237	LSR200	10069203
LCOL86	10073175	LGBP542	10070254	LSR200	10069205
LCOL86	10073177	LGBP542	10075673	LSR200	10069208
LCOL87	10068725	LGBP542	10075682	LSR200	10069214
LCOL87	10068731	LGBP542	10075704	LSR200	10069218
LCOL87	10068734	LGBP542	10075707	LSR200	10069998
LCOL87	10068739	LGBP542	10075708	LSR200	10070179
LCOL87	10068740	LGBP542	10075711	LSR200	10070182
LCOL87	10068743	LGBP542	10075718	LSR200	10070186
LCOL87	10068748	LGBP542	10075719	LSR200	10071840

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HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS

+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LCOL87	10068753	LGBP542	10075727	LSR200	10071843
LCOL99	10035394	LGBP542	10075736	LSR200	10071851
LCOL99	10035399	LGBP542	10075737	LSR200	10071854
LCOL99	10067243	LGBP542	10075745	LSR200	10072360
LCOL99	10067250	LGBP542	10075758	LSR200	10072364
LCOL99	10067255	LGBP542	10075764	LSR200	10074244
LCOL99	10067266	LGBP542	10075767	LSR200	10074246
LGBP286	10033189	LGBP542	10075773	LSR200	10074247
LGBP286	10033195	LGBP542	10075783	LSR200	10074249
LGBP286	10033198	LGBP542	10075790	LSR200	10075885
LGBP286	10033202	LGBP542	10075795	LSR200	10075893
LGBP286	10033658	LGBP542	10075798	LSR200	10075897
LGBP286	10033661	LGBP542	10075809	LSR200	10075908
LGBP286	10033664	LGBP542	10075811	LSR284	10067186
LGBP286	10033666	LGBP542	10075816	LSR284	10067189
LGBP286	10033687	LGBP542	10075818	LSR284	10067203
LGBP286	10033691	LGBP553	10069185	LSR284	10067212
LGBP286	10033694	LGBP553	10069189	LSR284	10070384
LGBP286	10033696	LGBP553	10069192	LSR289	10070061
LGBP286	10055095	LGBP553	10069198	LSR289	10070088
LGBP286	10055101	LGBP553	10074300	LSR289	10070106
LGBP286	10055110	LGBP553	10074307	LSR289	10070110
LGBP286	10055128	LGBP553	10074317	LSR320	10069098
LGBP286	10066559	LGBP553	10074320	LSR320	10069101
LGBP286	10066565	LGBP559	10055085	LSR320	10069104
LGBP286	10066570	LGBP559	10055088	LSR320	10069107
LGBP286	10066574	LGBP559	10055091	LSR320	10069118
LGBP286	10066581	LGBP559	10055105	LSR320	10069124
LGBP286	10066586	LGBP559	10067614	LSR320	10069127
LGBP286	10066589	LGBP559	10067619	LSR320	10069142
LGBP286	10066593	LGBP559	10067624	LSR320	10069146
LGBP286	10067309	LGBP559	10067627	LSR320	10069149
LGBP286	10067314	LGBP559	10069802	LSR320	10069152
LGBP286	10067323	LGBP559	10069805	LSR320	10069155
LGBP286	10067336	LGBP559	10069810	LSR320	10070019
LGBP286	10068683	LGBP559	10069882	LSR320	10070025
LGBP286	10068687	LGBP560	10067167	LSR320	10070041
LGBP286	10068689	LGBP560	10067169	LSR320	10070059
LGBP286	10068692	LGBP560	10067172	LSR320	10070076
LGBP286	10068697	LGBP560	10067179	LSR320	10070099
LGBP286	10068720	LGBP560	10068502	LSR320	10070102
LGBP286	10068723	LGBP560	10068509	LSR320	10070109
LGBP286	10068728	LGBP560	10068517	LSR320	10070111
LGBP286	10068836	LGBP560	10068522	LSR320	10070123

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+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP286	10068842	LGBP560	10074516	LSR320	10070132
LGBP286	10071929	LGBP560	10074521	LSR320	10070144
LGBP286	10071932	LGBP560	10074525	LSR320	10074102
LGBP286	10071937	LGBP560	10074531	LSR78	10033716
LGBP286	10071940	LGBP588	10066512	LSR78	10033721
LGBP286	10071936	LGBP588	10066526	LSR78	10033723
LGBP286	10071944	LGBP588	10066537	LSR78	10033727
LGBP286	10071947	LGBP588	10066545	LSR78	10035210
LGBP286	10071964	LGBP588	10066562	LSR78	10035220
LGBP286	10072430	LGBP588	10066564	LSR78	10035226
LGBP286	10072435	LGBP588	10066571	LSR78	10035232
LGBP286	10072444	LGBP588	10066625	LSR78	10068554
LGBP286	10072450	LGBP588	10066628	LSR78	10068556
LGBP286	10072989	LGBP588	10066633	LSR78	10069539
LGBP286	10073008	LGBP588	10066642	LSR78	10068543
LGBP286	10073027	LGBP588	10066800	LSR78	10068544
LGBP286	10073037	LGBP588	10067863	LSR78	10069535
LGBP286	10073048	LGBP588	10067879	LSR78	10069543
LGBP286	10073068	LGBP588	10067885	LSR78	10069548
LGBP286	10073072	LGBP588	10068209	LSR78	10069553
LGBP286	10073077	LGBP588	10068220	LSR78	10069562
LGBP314	10028037	LGBP588	10068224	LSR78	10069563
LGBP314	10028042	LGBP588	10068230	LSR78	10069565
LGBP314	10028045	LGBP588	10068234	LSR78	10072905
LGBP314	10028047	LGBP588	10068240	LSR78	10072909
LGBP314	10032998	LGBP588	10068246	LSR78	10072916
LGBP314	10033015	LGBP588	10068247	LSR78	10072924
LGBP314	10033026	LGBP588	10068249	LSR78	10074619
LGBP314	10033705	LGBP588	10068324	LSR78	10074621
LGBP314	10033711	LGBP588	10068331	LSR78	10074625
LGBP314	10033717	LGBP588	10068338	LSR78	10074629
LGBP314	10033718	LGBP588	10072242	LSR80	10075817
LGBP359	10029457	LGBP588	10072245	LSR80	10075819
LGBP359	10029472	LGBP588	10072247	LSR80	10075827
LGBP359	10034996	LGBP588	10072252	LSR80	10075831
LGBP359	10035002	LGBP588	10072256	LSR80	10074490
LGBP359	10035004	LGBP588	10072259	LSR80	10074497
LGBP359	10035006	LGBP588	10072264	LSR80	10074503
LGBP362	10069362	LGBP588	10072268	LSR80	10074509
LGBP362	10069369	LGBP588	10072265	LSR80	10074513
LGBP436	10030743	LGBP588	10072270	LSR80	10074534
LGBP436	10030757	LGBP588	10072273	LSR80	10074552
LGBP436	10030769	LGBP588	10072292	LSR80	10028029
LGBP436	10030775	LGBP588	10074284	LSR80	10028031

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HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS

+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP436	10034466	LGBP588	10074290	LSR80	10028034
LGBP436	10034611	LGBP588	10074291	LSR80	10028036
LGBP436	10066456	LGBP588	10074294	LSR80	10056329
LGBP436	10066462	LGBP588	10074296	LSR80	10056353
LGBP436	10066466	LGBP588	10074418	LSR80	10056355
LGBP436	10066469	LGBP588	10074422	LSR80	10056361
LGBP436	10066629	LGBP588	10074431	LSR80	10056365
LGBP436	10066630	LGBP588	10074438	LSR80	10056375
LGBP436	10066631	LGBP588	10074443	LSR80	10056380
LGBP436	10066634	LGBP588	10074447	LSR80	10056384
LGBP436	10066636	LGBP588	10074452	LSR80	10062146
LGBP436	10066637	LGBP602	10070104	LSR80	10062162
LGBP436	10066639	LGBP602	10070113	LSR80	10062182
LGBP436	10066641	LGBP602	10070119	LSR80	10062193
LGBP436	10068578	LGBP602	10070125	LSR80	10066584
LGBP436	10068581	LGBP602	10070127	LSR80	10066587
LGBP436	10068585	LGBP602	10070131	LSR80	10066592
LGBP436	10068590	LGBP602	10070134	LSR80	10066595
LGBP436	10068592	LGBP602	10070137	LSR80	10066598
LGBP436	10068606	LGBP602	10070138	LSR80	10066656
LGBP436	10068622	LGBP602	10070145	LSR80	10066718
LGBP436	10068629	LGBP602	10070178	LSR80	10066727
LGBP436	10072428	LGBP602	10070181	LSR81	10033604
LGBP436	10072433	LGBP602	10073164	LSR81	10033607
LGBP436	10072437	LGBP602	10073169	LSR81	10033611
LGBP436	10072448	LGBP602	10073182	LSR81	10033617
LGBP436	10072441	LGBP602	10073185	LSR81	10033675
LGBP436	10072453	LGBP602	10073188	LSR81	10033688
LGBP436	10072463	LGBP602	10073190	LSR81	10033690
LGBP436	10072472	LGBP602	10073195	LSR81	10033692
LGBP436	10073180	LGBP602	10073196	LSR81	10036321
LGBP436	10073191	LGBP602	10073201	LSR81	10036327
LGBP436	10073194	LGBP602	10073206	LSR81	10036330
LGBP436	10073238	LGBP602	10073210	LSR81	10036437
LGBP436	10073252	LGBP602	10073214	LSR81	10036438
LGBP436	10073264	LGBP602	10073459	LSR81	10036440
LGBP436	10073268	LGBP602	10073468	LSR81	10036442
LGBP436	10073272	LGBP602	10073474	LSR81	10036444
LGBP462	10069614	LGBP602	10073481	LSR81	10056219
LGBP462	10069619	LGBP602	10073488	LSR81	10056243
LGBP462	10069623	LGBP602	10073502	LSR81	10056251
LGBP462	10069626	LGBP602	10073510	LSR81	10056255
LGBP462	10074627	LGBP602	10075855	LSR81	10066644
LGBP462	10074716	LGBP602	10075857	LSR81	10066645

URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)
HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS
+ ADAPTIVE TISSUE TECHNOLOGY
(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)
(Specific Lots of Codes HAR23 and HAR36)

Kit Code	Kit Lot Number	Kit Code	Kit Lot Number	Kit Code	Kit Lot Number
LGBP462	10074723	LGBP602	10075860	LSR81	10066646
LGBP462	10074731	LGBP602	10075877	LSR81	10066647
LGBP468	10033492	LGBP602	10075890	LSR81	10066648
LGBP468	10035294	LGBP602	10075898	LSR81	10066732
LGBP468	10035302	LGBP602	10075910	LSR81	10066742
LGBP468	10035311	LGBP602	10075911	LSR81	10066752
LGBP468	10035317	LGBP602	10075913	LSR81	10067301
LGBP468	10035325	LGBP602	10075916	LSR81	10067305
LGBP468	10035371	LGBP602	10075918	LSR81	10067306
LGBP491	10034434	LGBP602	10075921	LSR81	10067310
LGBP491	10034538	LSR114	10029789	LSR81	10071904
LGBP491	10034577	LSR114	10029803	LSR81	10072969
LGBP491	10034584	LSR114	10029808	LSR81	10072973
LGBP491	10034596	LSR114	10029811	LSR81	10072988
LGBP491	10034605	LSR114	10029816	LSR81	10072991
LGBP505	10030137	LSR114	10029819	LSR81	10072994
LGBP505	10030141	LSR158	10028023	LSR81	10073096
LGBP505	10030162	LSR158	10028014	LSR81	10073100
LGBP505	10030163	LSR158	10028017	LSR81	10073102
LGBP505	10030166	LSR158	10028021	LSR81	10073106
LGBP505	10030167	LSR158	10028280	LSR81	10073110
LGBP505	10030169	LSR158	10028299	LSR81	10073116
LGBP505	10030172	LSR158	10028305	LSR81	10073125
LGBP505	10030179	LSR158	10028310	LSR81	10074694
LGBP505	10030187	LSR158	10028636	LSR81	10074696
LGBP505	10030199	LSR158	10030341	LSR81	10074698
LGBP505	10030211	LSR158	10030343	LSR81	10074702
LGBP505	10033848	LSR158	10032321	LSR81	10074701
LGBP505	10033851	LSR158	10033087	LSR81	10071918
LGBP505	10033948	LSR158	10033094	LSR81	10071927
LGBP505	10033950	LSR158	10033099	LSR81	10071934

The medical assessment concluded that this situation may cause inadvertent mechanical or thermal damage to unintended tissue if the continuous or inadvertent activation occurs when used in operative cases.

To date, Ethicon has not received any reports of adverse events associated with the issue that led to this recall. Health care practitioners who have treated patients using HARMONIC ACE®+ Shears with Adaptive Tissue Technology should follow those patients post-operatively in the usual manner with no additional action required.

We have identified the root cause and we have implemented immediate corrective actions to address the issue. Refer to Attachment 1 for assistance in identifying the product lots subject to this recall.

URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)

**HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS
+ ADAPTIVE TISSUE TECHNOLOGY
(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)
(Specific Lots of Codes HAR23 and HAR36)**

This recall does NOT affect any other lots for HARMONIC ACE®+ devices other than the lots shown above. Additionally, this recall does NOT affect any other HARMONIC® products.

IDENTIFICATION OF PRODUCT LOTS SUBJECT TO THIS RECALL:

Product lots subject to the recall in your inventory can be identified by product code and lot number (see product code and lot listing above). All unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology product lots subject to this recall are required to be returned. The product codes and lot numbers can be determined by using the Product Identification Tool within Attachment 1. Kit codes and lots that contain devices subject to this recall can be found in Table 2 above.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have any product lots or kits subject to this recall on hand and quarantine such product(s).
2. Remove the products or kits subject to this recall from your inventory and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. If any product lots subject to this recall have been forwarded to another facility, contact that facility to arrange return.
3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and fax or email it 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 recall.**
4. Customers are required to return all unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology or kits subject to this recall that are in their inventory immediately. Only unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology subject to this recall returned by August 31, 2018 will be eligible for replacement. Any unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology subject to this recall returned after August 31, 2018 will not be eligible for replacement.
5. To return unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology or kits subject to this recall, photocopy the completed BRF, place it in the box with the subject products, and affix the pre-paid authorized shipping label included with this recall notification letter. **[INSERT AFFILIATE NAME]** will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by contacting **[INSERT AFFILIATE NAME]** or **[INSERT PHONE NUMBER]**.

If you require any assistance with returning product lots subject to this recall, please contact **[INSERT AFFILIATE NAME]** or **[INSERT PHONE NUMBER]**.

We recognize the recall of the HARMONIC ACE®+ Shears with Adaptive Tissue Technology may be disruptive to your facility and we apologize for any inconvenience this may cause.

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

URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)
HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS
+ ADAPTIVE TISSUE TECHNOLOGY
(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)
(Specific Lots of Codes HAR23 and HAR36)

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 your local Sales Representative.

Attachments:

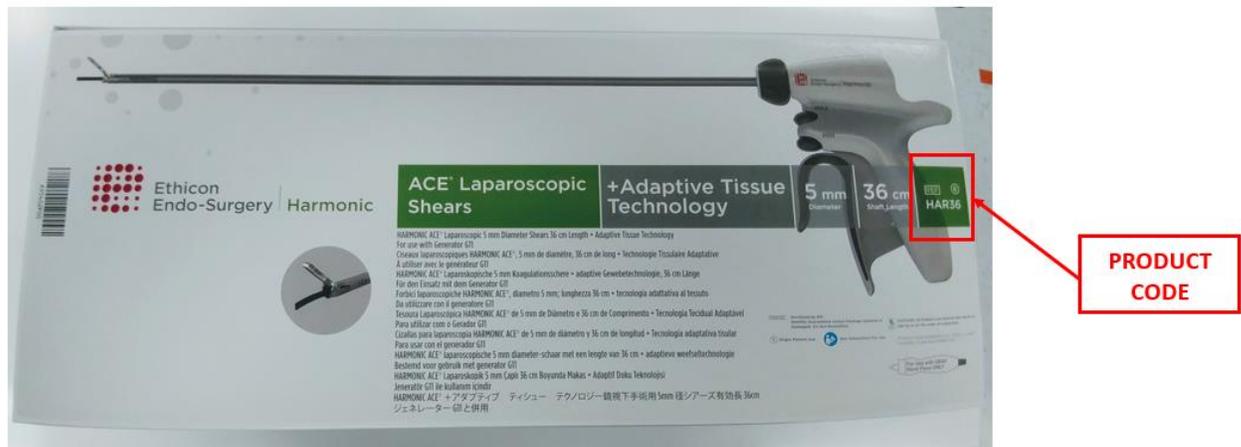
- Attachment 1: Product Identification Tool
- Attachment 2: Business Reply Form

ATTACHMENT 1: Product Identification Tool for HARMONIC ACE® (Specific Product Codes and Lots Above)

This tool will help customers identify product lots of HARMONIC ACE®+ Shears with Adaptive Tissue Technology subject to this recall by using the packaging labels. Please refer to table above for a list of all product lots subject to this recall.

SALES UNIT BOX (CONTAINING (6) SEALED TYVEK TRAYS)

FRONT OF SALES UNIT BOX



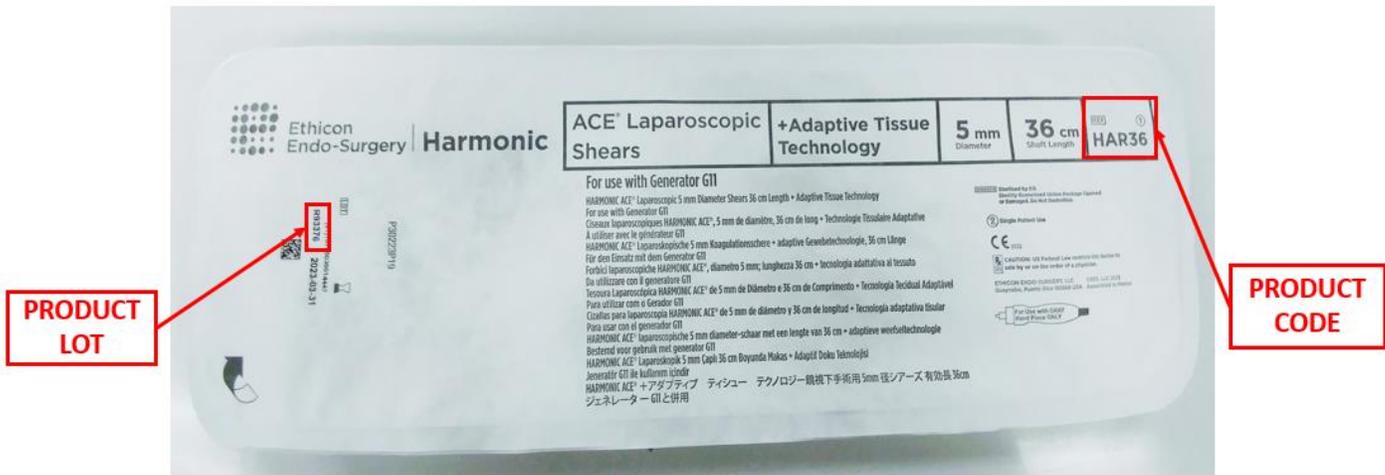
URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)
HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS
+ ADAPTIVE TISSUE TECHNOLOGY
(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)
(Specific Lots of Codes HAR23 and HAR36)

LABEL ON SALES UNIT BOX



TYVEK TRAY (CONTAINING (1) HARMONIC ACE®+ DEVICE)

TOP OF TYVEK TRAY



URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)

HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS

+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

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] or e-mail the form to [INSERT AFFILIATE EMAIL ADDRESS] within 3 business days, even if you do not have the product subject to this recall to return.

If you have product subject to this recall to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Product Inventory – please check one:

- We have **NO** HARMONIC ACE®+ lots subject to this recall.
- We have HARMONIC ACE®+ lots subject to this recall and are returning the following products:

PRODUCT NAME	PRODUCT CODE	LOT NUMBERS			Total Quantity Returning ¹ ('Eaches')
HARMONIC ACE®+ Shears with Adaptive Tissue Technology (23CM Length)	HAR23				
	HAR23				
	HAR23				
HARMONIC ACE®+ Shears with Adaptive Tissue Technology (36CM Length)	HAR36				
	HAR36				
	HAR36				

¹Note: Each Sales Unit Box contains (6) eaches / devices.

Kit Code	Kit Lot Number	Quantity Returning (Eaches)

URGENT: VOLUNTARY MEDICAL DEVICE RECALL (REMOVAL)

HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS

+ ADAPTIVE TISSUE TECHNOLOGY

(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)

(Specific Lots of Codes HAR23 and HAR36)

[Account Name]

[Account Address]

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