

**URGENT: FIELD SAFETY CORRECTIVE ACTION - 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)**

**Date: 10-May-2018**

Dear Distributor, Operating Room Supervisors, and Materials Management Personnel:

**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:**

**Table A – Products Subject to this Correction**

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS			
<b>HARMONIC ACE®+ Shears with Adaptive Tissue Technology (23CM Length)</b>	<b>HAR23</b>	P9125C	P93V06	P93Z96	P94E6U
		P91F4A	P93W0A	P9400F	P94G1W
		P91F86	P93W4Y	P9409V	P94H32
		P93M3W	P93W8A	P94A93	
		P93T5J	P93Y4A	P94A94	
		P93T5K	P93Z4X	P94C8R	
<b>HARMONIC ACE®+ Shears with Adaptive Tissue Technology (36CM Length)</b>	<b>HAR36</b>	N93923	P91L6E	P93U17	P94C47
		N9392K	P91L6J	P93U91	P94C5R
		N93978	P9396A	P93V02	P94C8T
		P9123A	P9396C	P93V03	P94D3J
		P9129W	P9399T	P93V0V	P94D3K
		P91301	P93A1L	P93V0W	P94D5G
		P91394	P93L47	P93V5T	P94D7Z
		P9139N	P93L76	P93X2X	P94D9K
		P9144R	P93M0K	P93X4E	P94E1Z
		P9148K	P93M0L	P93X65	P94E20
		P9149J	P93M5Y	P93X85	P94E3Z
		P9168K	P93M6T	P93X98	P94E8W
		P9173R	P93N01	P93X9E	P94F1M
		P91749	P93N3X	P93Y47	P94F3A
		P9174K	P93N3Y	P93Y48	P94F5T
		P91795	P93N5A	P93Y8X	P94F6C
		P9179U	P93P09	P93Z4T	P94F7L
		P91C51	P93P26	P93Z5X	P94G1G
		P91C83	P93P7H	P93Z95	P94G1H
		P91D30	P93R10	P94015	P94G1J
		P91F2X	P93R4F	P9405H	P94H0J
		P91K68	P93R4G	P9409W	P94H0K
		P91K69	P93R56	P9410Z	P94H31
		P91L0H	P93R6V	P9414T	P94H4V
		P91L0J	P93T0X	P94A5K	P94H8J
		P91L1Y	P93T9L	P94A6A	
		P91L1Z	P93T9M	P94C11	

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.

**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.**

#### **ACTION REQUIRED:**

1. Examine your inventory immediately to determine if you have product lots subject to this recall on hand and quarantine such product(s).
2. Remove the product lots subject to this recall 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. Please complete the Business Reply Form (Attachment 2) confirming receipt of this notice and return it to your Ethicon sales representative within five (5) business days. **Please return the BRF even if you do not have the product lots subjected to this recall.**
4. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.
5. Keep this notice visibly posted for awareness until all product lots subject to this recall have been returned to your Ethicon sales representative. While processing your returns, please maintain a copy of this notice with the product lots subject to this recall and keep a copy for your records.

If you require any assistance with returning product lots subject to this recall, please contact your Ethicon sales representative.

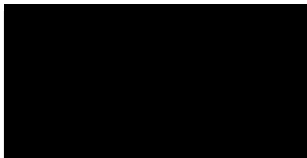
We recognize the recall of the HARMONIC ACE®+ Shears with Adaptive Tissue Technology may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this medical device correction (notification) or to report any customer complaints, please contact your Ethicon sales representative.

**Attachments:**

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

Yours sincerely,



Lee Ching Hwee  
Regulatory Affairs Manager

cc: Chairman Medical Board  
Relevant Head of Departments

URGENT: FIELD SAFETY CORRECTIVE ACTION - 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)



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**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**



**PRODUCT  
CODE**

**LABEL ON SALES UNIT BOX**



**PRODUCT  
LOT**



Johnson & Johnson Medical Singapore  
a division of Johnson & Johnson Pte Ltd.  
2 Science Park Drive, #07-13, Ascent, Singapore Science Park 1, Singapore 118222  
Tel: +65 6918 8000  
Business Reg No. 52836279L Company Reg No. 197402104W

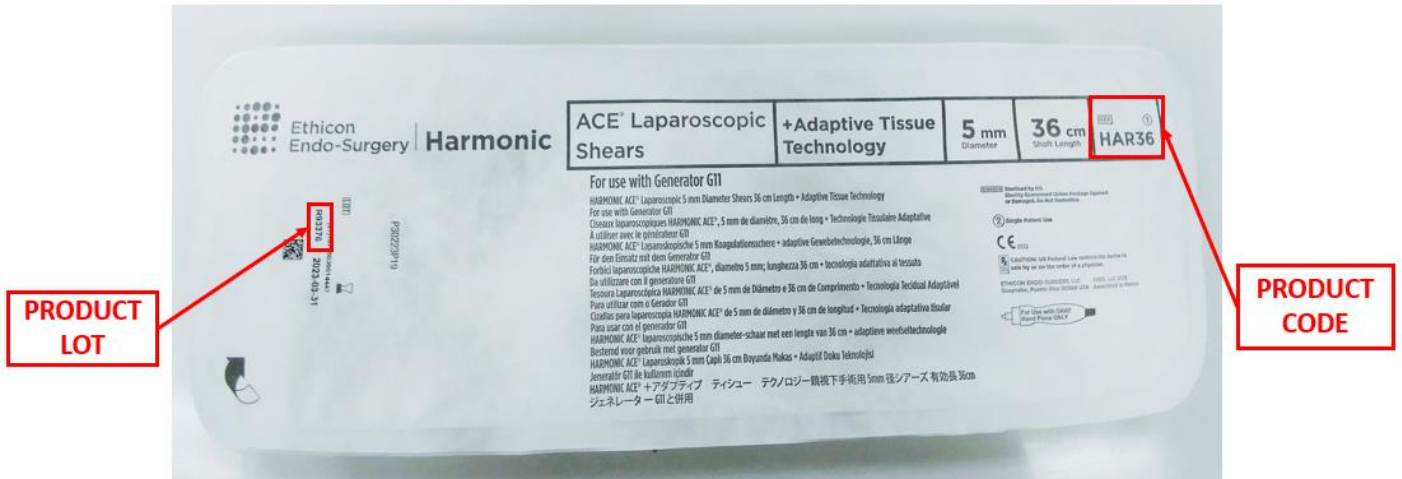
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**TYVEK TRAY (CONTAINING (1) HARMONIC ACE®+ DEVICE)**

**TOP OF TYVEK TRAY**



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 Tel: +65 6918 8000  
 Business Reg No. 52836279L Company Reg No. 197402104W



**ATTACHMENT 2: Business Reply Form (BRF)**

Your timely response to this customer notification is requested. Please complete and return this form to your Ethicon sales representative **within 5 business days, even if you do not have the product lots subject to this recall to return.**

If you have product lots 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 <sup>1</sup> ('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				

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

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

\_\_\_\_\_  
Customer Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature & Date

\_\_\_\_\_  
Stamp (Stamp shall bear facility name)

Please complete this Verification Section and return to your Ethicon representative within **(5) five business days** of receipt of the Field Safety Notice.

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