

**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**

18<sup>th</sup> May 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	P93T5K
		P94A93	P94A94

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS		
HARMONIC ACE®+ Shears with Adaptive Tissue Technology (36CM Length)	HAR36	P91D30	P9139N	P9399T
		P91L1Y	P91K68	P93N01
		N93978	P91C83	P93M0L
		P93Z4T	P94E20	

**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)**

Table 2. Kit Codes with affected Lots to this notification

<b>Kit Code</b>	<b>Kit Lot Number</b>	
<b>LSR313</b>	10068424	10069239
	10068435	10069245
	10068437	10074125
	10068442	10074130
	10069248	10074128
	10069261	

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. 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.

## **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)**

3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and fax or email it to **MDFieldActionsUKIRL@its.jnj.com** or **0113 307 1808** 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. Keep this notice visibly posted for awareness until all product lots subject to this recall have been returned. 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.
5. To return unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology product lots subject to this recall provide collection details on your completed BRF and send this to **MDFieldActionsUKIRL@its.jnj.com**, once arranged photocopy the completed BRF, place it in the box with the subject products, and affix the documents provided by our returns department.

If you require any assistance with returning product lots subject to this recall, please contact [MDFieldActionsUKIRL@its.jnj.com](mailto:MDFieldActionsUKIRL@its.jnj.com).

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 [MDFieldActionsUKIRL@its.jnj.com](mailto:MDFieldActionsUKIRL@its.jnj.com)

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

# 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 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

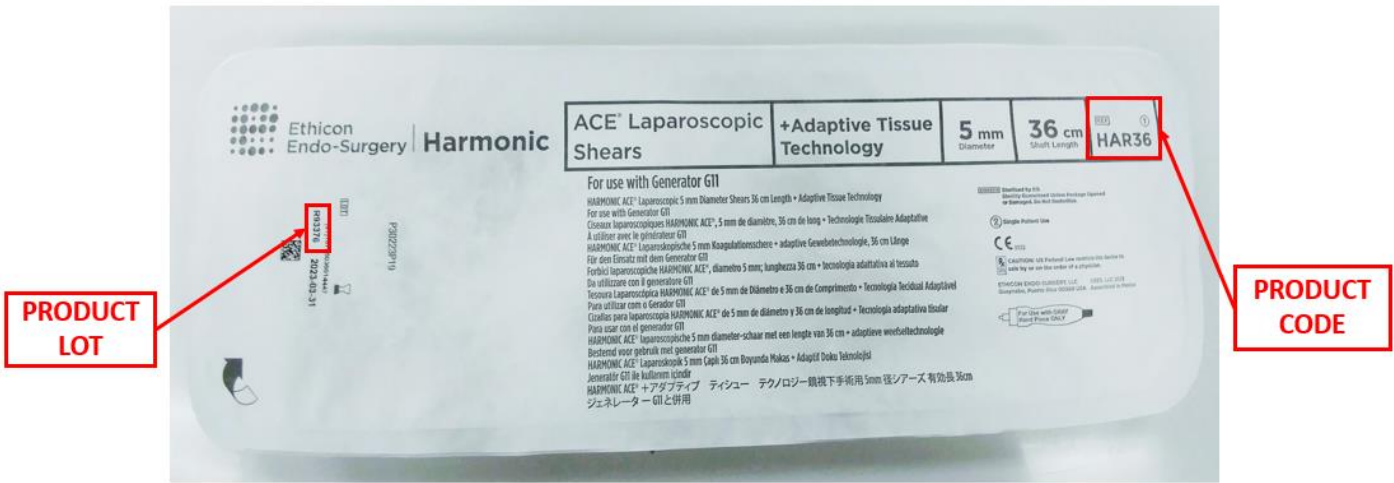


#### LABEL ON SALES UNIT BOX



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

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**TOP OF TYVEK TRAY**



**PRODUCT  
LOT**

**PRODUCT  
CODE**

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

Your timely response to this customer notification is requested. Please complete and fax this form to fax number **0113 307 1808** or e-mail the form to **MDFieldActionsUKIRL@its.jnj.com** within 3 business days, even if you **DO NOT** have the product lots 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 <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.

Kit Code	Kit Lot Number/s					Quantity Returning (Eaches)

Print Name of Person Completing Business Reply Form:	Telephone Number:
Hospital Name & Address:	Date:
Collection Department and Collection 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>	