ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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 Distributor:

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	

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.

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+ ADAPTIVE TISSUE TECHNOLOGY
(HARMONIC ACE®+ Shears with Adaptive Tissue Technology)
(Specific Lots of Codes HAR23 and HAR36)

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 any product lot subject to this recall on hand and quarantine such product(s).

2. Remove the product lot subject to this recall and communicate the issue to relevant materials management personnel, or anyone else in your facility who needs to be informed.

3. It is not necessary to contact your accounts regarding this recall. Ethicon will directly communicate with customers about the above listed product lot subject to this recall.

4. 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 lot subject to this recall.**

5. Customers are required to return all unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology 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 reimbursement. Any unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology subject to this recall returned after August 31, 2018 will not be eligible for reimbursement.

6. To return unused HARMONIC ACE®+ Shears with Adaptive Tissue Technology 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].

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.

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(Specific Lots of Codes HAR23 and HAR36)

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

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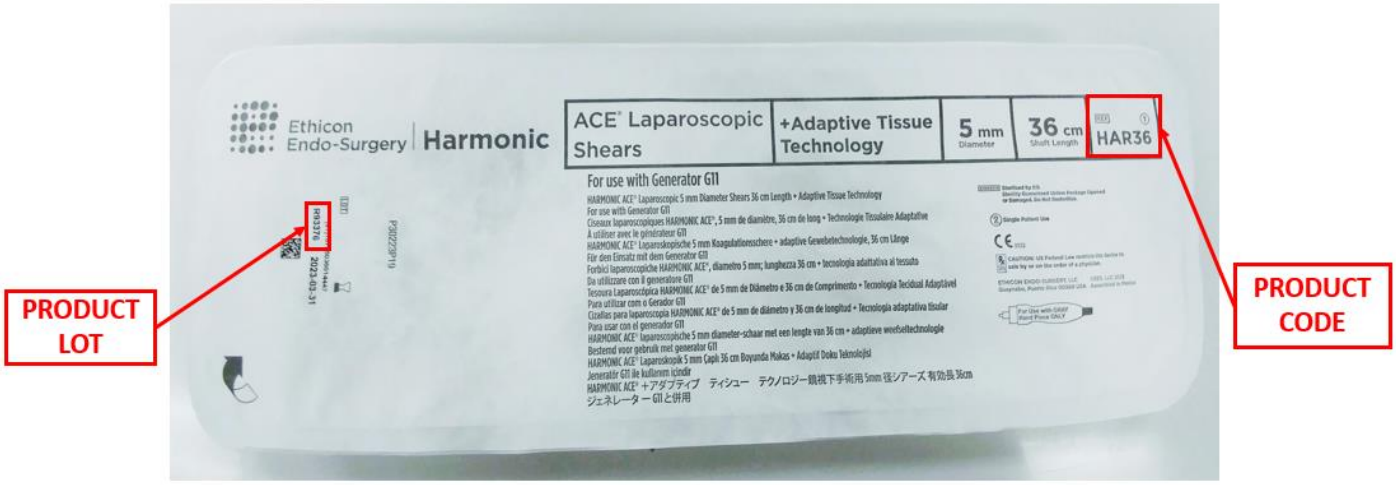
LABEL ON SALES UNIT BOX

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

TOP OF TYVEK TRAY



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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 [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 lot 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				

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

[Account Name]
[Account Address]

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