ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

HARMONIC™ HD 1000i Shears

(Specific Lots of Product Codes HARHD20 and HARHD36)

TW: 1990841

[27-Jul-2021]

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

Ethicon has initiated a voluntary medical device recall (removal) of specific lots of HARMONIC® HD 1000i Shears. Ethicon has identified a rare condition in a small number of devices in which an internal component may be cracked and become lodged behind the energy button potentially resulting in continuous activation of the device. The surgeon may be able to quickly detect the device continuous activation issue during a procedure through audio, visual, and tactile indicators.

Potential Impact:
In the unlikely event that continuous activation occurs, a surgical delay may result while an alternate device is obtained, or an alternate method is employed to complete the procedure. The delay should not result in any impact to the expected surgical outcome. Should the user not recognize continuous activation, inadvertent thermal damage to unintended tissue may occur during surgery.

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™ HD 1000i Shears should follow those patients post-operatively in the usual manner with no additional action required, as the identified issue occurs during surgery.

Ethicon has determined the root cause of this issue, identified the specific lots impacted, and implemented corrective actions to address the issue and prevent reoccurrence.

This voluntary medical device recall has been communicated to all impacted Health Authorities, including the local Health Authority of your country.

Records indicate that you may have ordered or received product subject to this recall. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE HARMONIC™ HD 1000i SHEARS**.

The earliest date of distribution for the affected product was **September 3, 2020**.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE AFFECTED LOTS LISTED IN ATTACHMENT 1. REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL:

Product subject to the recall in your inventory can be identified by product code and lot described in **Attachment 1**. Please utilize **Attachment 2** for assistance in identifying the product lots subject to this recall. All unused HARMONIC™ HD 1000i Shears subject to this recall are required to be returned.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s).

2. Remove the product 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.

3. If any product subject to this action has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.

4. Complete the Business Reply Form (BRF) (Attachment 5) confirming receipt of this notice and return to [JnJ-MD-FSCARecall@ITS.JNJ.com] within three (3) business days. **Please return the BRF even if you do not have product subject to this recall.**

5. Customers are required to return unused affected HARMONIC™ HD 1000i Shears subject to this recall that are in their inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no later than January 31, 2022. Any non-affected product and any product returned after the date specified will not receive credit reimbursement.

6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to the authorized distributor and franchise While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.

At Ethicon, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this voluntary product recall or require any assistance with returning product, please contact [JnJ-MD-FSCARecall@ITS.JNJ.com]

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to [MDDCOMP@JNJAE.JNJ.COM]

Attachments:

Attachment 1: Affected Product Codes and Lots
Attachment 2: Product Identification Tool
Attachment 3: Business Reply Form (BRF)

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Attachment 1: Affected Product Codes and Lots

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS		GTIN / PRIMARY DI NUMBER
HARMONIC™ HD 1000i Shears (20cm Shaft Length)	HARHD20	U95126	U9571N	10705036015048
		U9526Z	U95A80	
		U9543P	U95T0X	
		U9550G	U95U1R	
HARMONIC™ HD 1000i Shears (36cm Shaft Length)	HARHD36	U94Y9V	U95814	10705036015055
		U94Y9W	U95815	
		U94Z49	U95856	
		U94Z98	U9587D	
		U9503G	U95A9X	
		U9507E	U95C2A	
		U95127	U95D4T	
		U9512D	U95E1U	
		U9516E	U95E29	
		U9518D	U95E6F	
		U9521Z	U95E72	
		U9530P	U95F07	
		U95366	U95F2T	
		U95427	U95F6N	
		U9543R	U95F8W	
		U9548R	U95K4D	
		U95524	U95L0A	
		U95525	U95R4F	
		U95526	U95R7C	
		U9554U	U95T2Z	
		U95566	U95T90	
		U95599	U95U6A	
		U9564G	U95Y7G	
		U9569W	U95Z67	
		U9571P	U9523L	
		U95754	U9530X	

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Attachment 2: Product Identification Tool for HARMONIC™ HD 1000i Shears

Please refer to the below in order to identify location of product code, GTIN, and lot number for HARMONIC™ HD 1000i Shears subject to this recall by using the packaging labels.

Device Box – Front (Representative Sample)

Product Code

Device Box – Back (Representative Sample)

GTIN

Lot Number

Sealed Device Tyvek* Package (Representative Sample)

Product Code

Lot Number

*Tyvek is a trademark of E.I. du Pont de Nemours and Company or its affiliates

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Attachment 3: Business Reply Form

Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and fax or email it to [JnJ-MD-FSCARecall@ITS.JNJ.com] **within 3 business days, even if you do not have 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.

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 (If different from above) or reference PO for replacement shipment:	
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	

Product Inventory – *please check one*

☐ **We have NO inventory of product subject to this recall (removal).**

☐ **We have product subject to this recall (removal) and are returning the following products:**

PRODUCT CODE	PRODUCT LOT	QUANTITY RETURNING (EACHES)