ETHICON

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

URGENT: FIELD SAFETY NOTICE

HARMONIC™ HD 1000i Shears

(Specific Lots of Product Codes HARHD20 and HARHD36)

– Voluntary Product Recall (Removal) –

[Insert Date]

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**. **Attachment 2** has procedure pack codes and lot numbers that contain HARMONIC™ HD 1000i Shears subject to this recall. Please utilize **Attachment 3** and **Attachment 4** 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 [Insert Affiliate Information] 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 [Insert Affiliate Information]. 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 [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.

Attachments:

Attachment 1: Affected Product Codes and Lots
Attachment 2: Procedure Packs with HARMONIC™ HD 1000i Shears Affected Codes and Lots
Attachment 3: Product Identification Tool
Attachment 4: Procedure Pack Identification Tool
Attachment 5: 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: Procedure Packs with HARMONIC™ HD 1000i Shears Affected Codes and Lots

PROCEDURE PACK CODE	PROCEDURE PACK LOT	PROCEDURE PACK CODE	PROCEDURE PACK LOT	PROCEDURE PACK CODE	PROCEDURE PACK LOT
LCOL142	10221875	LGBP512P	10224497	LGBP721	10237790
LCOL142	10221866	LGBP512P	10224502	LGBP730	10232122
LCOL142	10221869	LGBP512P	10224504	LGBP730	10232126
LCOL142	10221871	LGBP512P	10224506	LGBP730	10232133
LCOL142	10221877	LGBP512P	10224963	LGBP730	10232137
LCOL142	10221914	LGBP512P	10224964	LGBP730	10237187
LCOL142	10234617	LGBP512P	10224966	LGBP730	10237190
LCOL142	10234619	LGBP512P	10224969	LGBP730	10237192
LCOL142	10234622	LGBP512P	10225024	LGBP730	10237194
LCOL142	10234626	LGBP512P	10225025	LGBP730	10237196
LCOL157	10221568	LGBP512P	10225029	LGBP730	10237198
LCOL157	10221572	LGBP512P	10225046	LGBP730	10237199
LCOL157	10221574	LGBP512P	10225051	LGBP730	10237202
LCOL157	10221753	LGBP512P	10225053	LGBP730	10240257
LCOL157	10221756	LGBP512P	10227918	LGBP730	10240263
LCOL157	10221759	LGBP512P	10227920	LGBP754	10231677
LCOL157	10221771	LGBP512P	10227924	LGBP754	10231702
LCOL157	10221773	LGBP512P	10227927	LGBP754	10231714
LCOL157	10221775	LGBP512P	10235418	LGBP754	10231727
LCOL157	10224303	LGBP512P	10235419	LGBPB741	10237255
LCOL157	10224316	LGBP512P	10235420	LGBPB741	10236770
LCOL157	10224321	LGBP512P	10235421	LGBPB741	10236774
LCOL157	10224325	LGBP512P	10239420	LGBPB741	10237250
LCOL157	10224329	LGBP512P	10239428	LGBPB741	10237260
LCOL157	10224332	LGBP512P	10239430	LGBPB741	10237278
LCOL157	10237546	LGBP512P	10239433	LGBPB741	10240386
LCOL157	10237551	LGBP513P	10221521	LGBPB741	10240392
LCOL157	10237559	LGBP513P	10221524	LGBPB741	10240400
LCOL172	10221193	LGBP513P	10221525	LGBPB741	10240403
LCOL172	10221199	LGBP513P	10221527	LHEP001	10232323
LCOL208	10221656	LGBP513P	10239422	LHEP001	10232328
LCOL208	10221647	LGBP513P	10239423	LHEP001	10232346
LCOL208	10221652	LGBP620	10232303	LHEP001	10232354
LCOL208	10221654	LGBP620	10232288	LHEP001	10232356
LCOL208	10224318	LGBP620	10232293	LHEP001	10232357
LCOL208	10224320	LGBP620	10232298	LHEP001	10232358
LCOL208	10224322	LGBP638	10222627	LHEP001	10232360
LCOL208	10224323	LGBP638	10222634	LSR329B	10223024
LCOL208	10236857	LGBP638	10222652	LSR329B	10223026
LCOL208	10236859	LGBP638	10222660	LSR329B	10223029
LCOL208	10236865	LGBP638	10229804	LSR329B	10223034
LCOL221B	10221587	LGBP638	10229807	LSR329B	10224456
LCOL221B	10221584	LGBP638	10229810	LSR329B	10224457
LCOL221B	10221585	LGBP641	10222916	LSR329B	10224458

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PROCEDURE PACK CODE	PROCEDURE PACK LOT	PROCEDURE PACK CODE	PROCEDURE PACK LOT	PROCEDURE PACK CODE	PROCEDURE PACK LOT
LCOL221B	10221586	LGBP641	10222917	LSR329B	10224460
LCOL221B	10221589	LGBP641	10222919	LSR329B	10232269
LCOL221B	10221590	LGBP641	10222920	LSR329B	10232274
LCOL221B	10221591	LGBP641	10222922	LSR329B	10232278
LCOL221B	10221592	LGBP641	10222923	LSR329B	10232283
LCOL221B	10221593	LGBP641	10222925	LSR329B	10241754
LCOL221B	10221595	LGBP641	10222927	LSR329B	10241765
LCOL221B	10221597	LGBP641	10222928	LSR360	10231589
LCOL221B	10221601	LGBP641	10222929	LSR360	10231573
LCOL231	10232545	LGBP641	10222932	LSR360	10231575
LCOL231	10232528	LGBP641	10222935	LSR360	10231581
LCOL231	10232540	LGBP641	10222941	LSR363B	10223376
LCOL231	10232544	LGBP641	10222944	LSR363B	10223348
LCOL231	10232551	LGBP641	10222977	LSR363B	10223356
LCOL231	10232555	LGBP641	10222980	LSR363B	10223371
LCOL231	10232556	LGBP641	10222984	LSR363B	10223908
LCOL231	10232558	LGBP641	10222986	LSR365	10241794
LCOL231	10232561	LGBP641	10234117	LSR365	10241766
LCOL231	10232566	LGBP641	10234121	LSR365	10241773
LCOL231	10232568	LGBP641	10234125	LSR365	10241779
LCOL231	10232569	LGBP641	10234129	LSR424	10224064
LCOL231	10232574	LGBP641	10234131	LSR424	10224067
LCOL231	10232578	LGBP641	10234138	LSR424	10224077
LCOL231	10232580	LGBP642	10235436	LSR424	10224086
LCOL231	10232586	LGBP642	10235441	LSR457	10223897
LCOL231	10232638	LGBP651	10208865	LSR457	10223891
LCOL231	10232647	LGBP651	10208873	LSR457	10223895
LCOL231	10232651	LGBP664	10210093	LSR457	10223896
LCOL231	10232657	LGBP664	10210102	LSR457	10223898
LCOL242	10222251	LGBP664	10210110	LSR457	10223899
LCOL242	10222200	LGBP664	10210117	LSR467B	10230055
LCOL242	10222204	LGBP664	10221519	LSR467B	10230056
LCOL242	10222246	LGBP664	10221522	LSR467B	10230058
LCOL242	10222258	LGBP664	10221526	VATS69	10227916
LCOL242	10222262	LGBP664	10221529	VATS69	10227923
LESOP7	10222586	LGBP664	10224333	VATS69	10237719
LESOP7	10222588	LGBP664	10224334	VATS69	10237720
LESOP7	10222596	LGBP664	10224335	VATS69	10237724
LESOP7	10222601	LGBP664	10224336	VATS69	10237725
LGBP512P	10208867	LGBP664	10234749	VATS69	10237726
LGBP512P	10208880	LGBP664	10234753	VATS69	10237727
LGBP512P	10208901	LGBP718	10224038	VATS85	10223996
LGBP512P	10208906	LGBP718	10224014	VATS85	10223977
LGBP512P	10220973	LGBP718	10224023	VATS85	10223985
LGBP512P	10220977	LGBP718	10224028	VATS85	10223990
LGBP512P	10220982	LGBP721	10237770		
LGBP512P	10220985	LGBP721	10237774		

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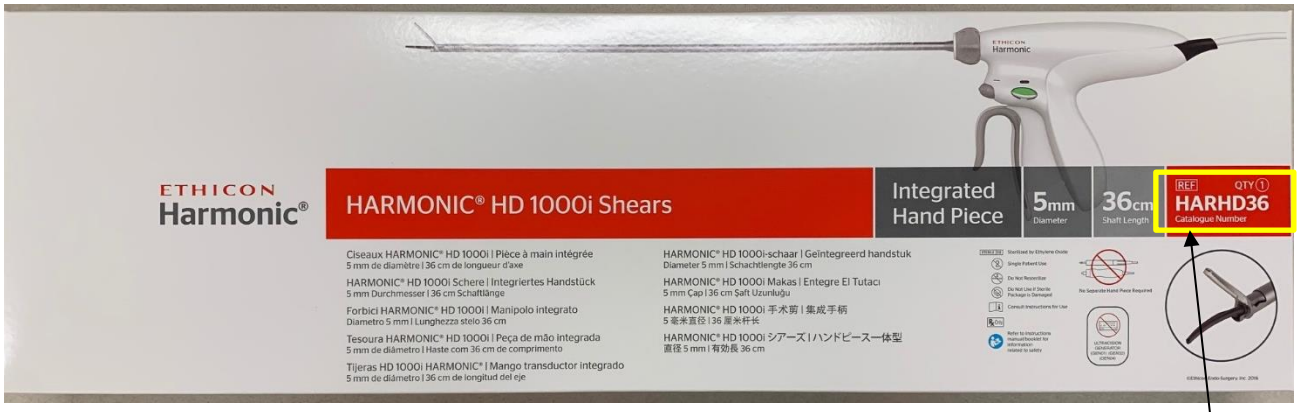
Attachment 3: Product Identification Tool for HARMONIC™ HD 1000i Shears

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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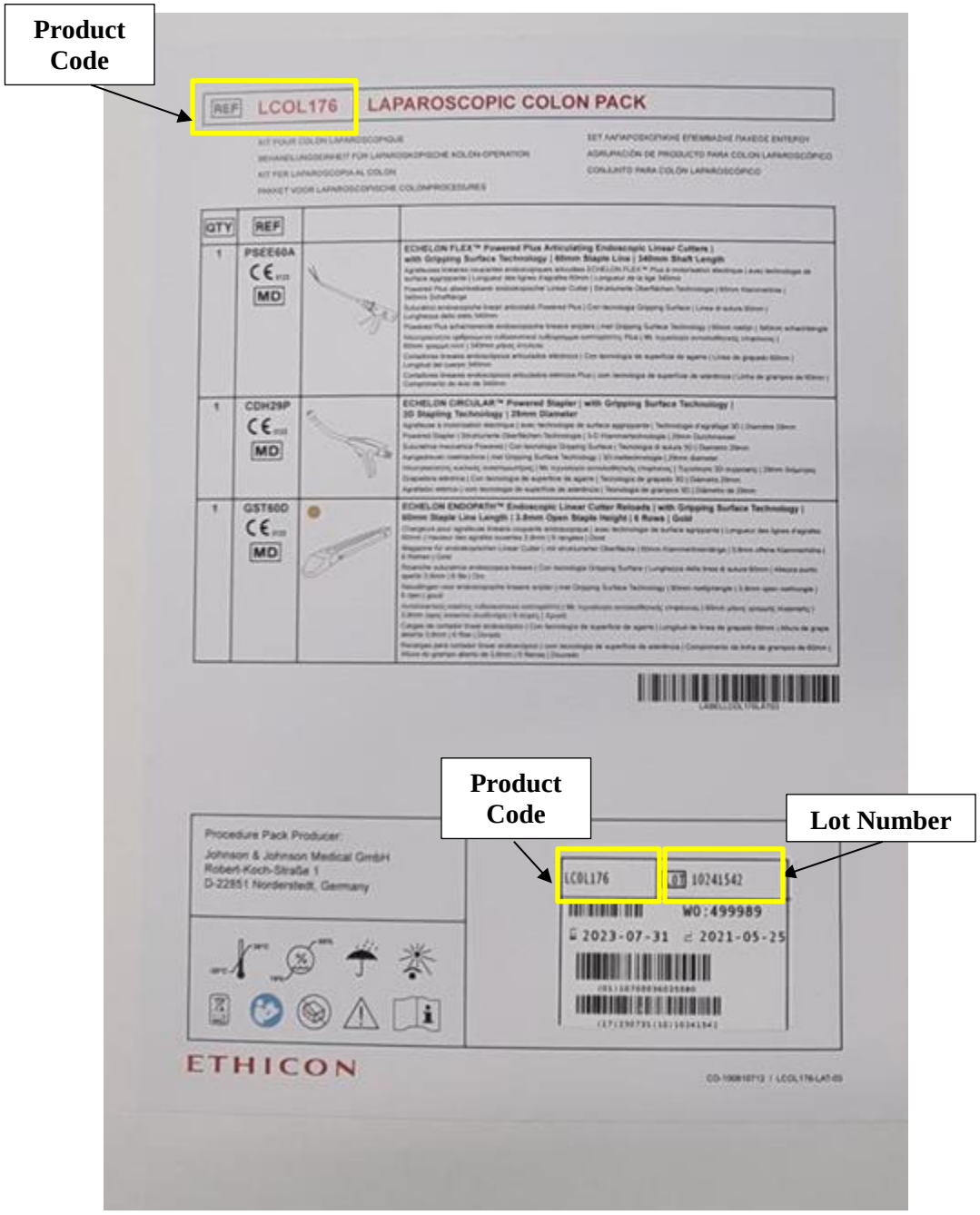
Attachment 4: Procedure Pack Identification Tool

This tool will help customers identify the location of Product Code and lot number of Procedure Packs subject to this recall by using the Procedure Pack packaging labels.

Procedure Pack Box (Representative Sample)



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Attachment 5: 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 [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 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)

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PROCEDURE PACK CODE	PROCEDURE PACK LOT	QUANTITY RETURNING (EACHES)