Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 JUN 2018

FDA ADVISORY
No. 2018-207

TO: **THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS**

SUBJECT: **VOLUNTARY RECALL OF HARMONIC ACE® LAPAROSCOPIC 5MM DIAMETER SHEARS + ADAPTIVE TISSUE TECHNOLOGY (SPECIFIC LOTS ONLY FOR CODES HAR23 AND HAR36)**

The Food and Drug Administration (FDA) informs the public and all concerned healthcare professionals that Johnson & Johnson Philippines, Inc. has voluntarily recalled specific lots of HARMONIC ACE® Laparoscopic 5mm Diameter Shears + Adaptive Tissue Technology (Specific Lots only for Codes HAR23 and HAR36), with the following impacted lot numbers:

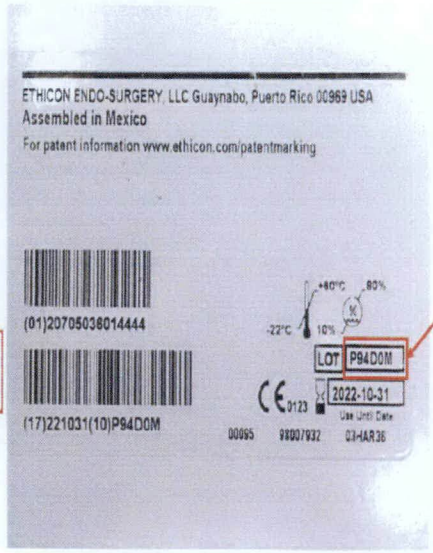
PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS			
HARMONIC ACE®+ Shears with Adaptive Tissue Technology (23CM Length)	**HAR23**	P9125C	P93W8A	P94A93	P94H9V
		P93T5J	P93Y4A	P94A94	P94J28
		P93T5K	P93Z4X	P94C8R	
		P93V06	P93Z96	P94E6U	
		P93W0A	P9400F	P94G1W	
		P93W4Y	P9409V	P94H32	
HARMONIC ACE®+ Shears with Adaptive Tissue Technology (36CM Length)	**HAR36**	N93923	P93M6P	P93U5N	P94C47
		N9392K	P93M6T	P93U90	P94C5R
		P9129W	P93N00	P93U91	P94C8T
		P91394	P93N01	P93V02	P94D0M
		P9139N	P93N3X	P93V03	P94D0P
		P9144R	P93N3Y	P93V0V	P94D3J
		P9148K	P93N5A	P93V57	P94D3K
		P9149J	P93N7H	P93V5T	P94D5G
		P9168K	P93P09	P93W9R	P94D9K
		P9173R	P93P26	P93W9X	P94E1Z
		P9174K	P93P2E	P93X2G	P94E20
		P91795	P93P7G	P93X2W	P94E3Z
		P91C51	P93P7H	P93X2X	P94E8W
		P91C83	P93R0Z	P93X85	P94F1M
		P91F2X	P93R10	P93X98	P94F3A
		P91K69	P93R4F	P93Y47	P94F5T
		P91L0H	P93R4G	P93Y48	P94F6C
		P91L1Y	P93R56	P93Y8X	P94F7L

		P91L6E	P93R57	P93Z4T	P94G1H
		P91L6J	P93R6U	P93Z5X	P94G1J
		P9396A	P93R6V	P93Z95	P94H0K
		P9396C	P93T0X	P94015	P94H31
		P9399T	P93T20	P9414T	P94H4V
		P93A1L	P93T26	P94A5K	P94H8J
		P93L47	P93T9L	P94A6A	
		P93L76	P93U0P	P94C10	
		P93M5Y	P93U17	P94C11	

SALES UNIT BOX (CONTAINING (6) SEALED TYVEK TRAYS)

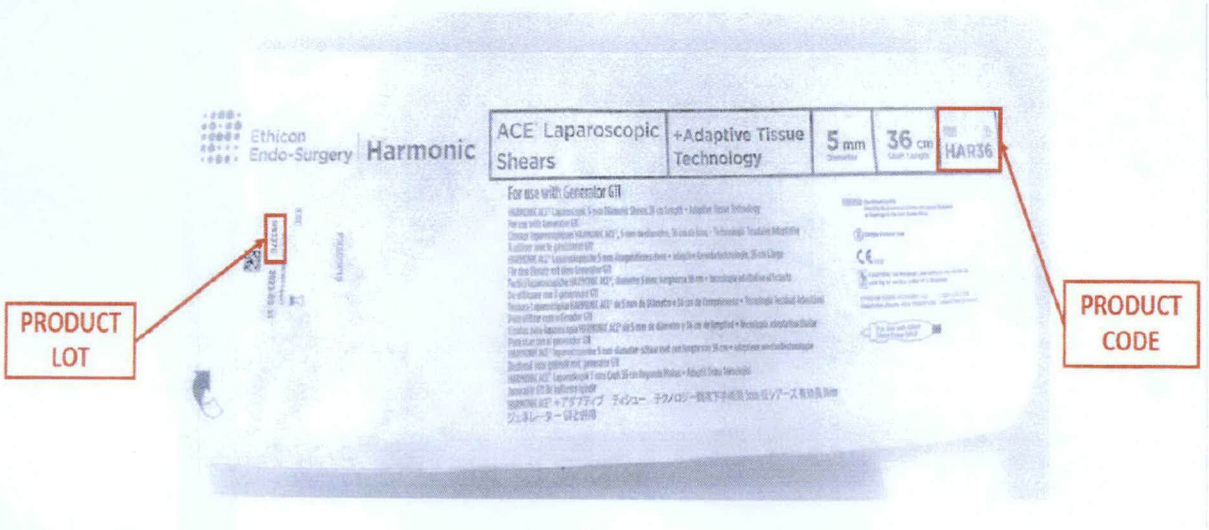
FRONT OF SALES UNIT BOX

LABEL ON SALES UNIT BOX



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

TOP OF TYVEK TRAY



Ethicon Endo-Surgery, LLC ("Ethicon"), the manufacturer of the above-mentioned products confirmed that some devices contained in theses lots may have been assembled with an internal component that may cause continuous or inadvertent activation of the device.

Based on their 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.

Distributors, retailers, hospitals and all healthcare professionals / users are advised to discontinue further distribution, sale and use of the said affected medical device product.

For more information and inquiries, please e-mail us at cdrrhr_prsdd@fda.gov.ph. or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 local 8301.

NELA CHARADE G. PUNO, RPh
Director General

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