Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-3545

21 DEC 2021

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of Harmonic® HD 1000i Shears**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected product codes and lots of Harmonic® HD 1000i Shears with FDA registration number, MDR-06660, manufactured by Ethicon Endo-Surgery S.A. de C.V., imported and distributed by Johnson & Johnson (Philippines) Inc.

Product Code	Description	Affected Lot Numbers	GTIN
HARHD36	Harmonic® HD 1000i Shears (36cm Shaft Length)	U95E1U U9523L	10705036015055

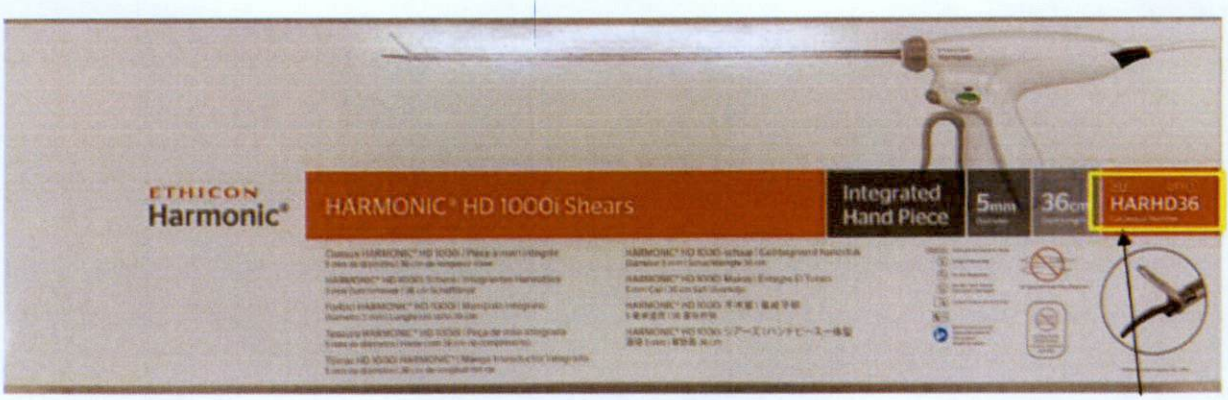

Figure 1. Harmonic® HD 1000i Shears

The manufacturer initiated the voluntary recall of the above-mentioned product code/lots of Figure 1. Harmonic® HD 1000i in response to the identified 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.

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.

In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected product code/lots of Harmonic® HD 1000i Shears.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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