Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 AUG 2019

FDA ADVISORY
No. 2019-255

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Product Recall of Proximate ILS Curved Intraluminal Stapler**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Proximate ILS Curved Intraluminal Stapler with DVR No. 4981, manufactured by Ethicon Endo-Surgery, LLC – Puerto Rico and imported by Johnson & Johnson (Phils.), Inc.:

Product Name	Product Code	Lot Number
Proximate ILS Curved Intraluminal Stapler	CDH21A CDH25A CDH29A CDH33A	All lots within expiration date range of December 2022 to March 2024

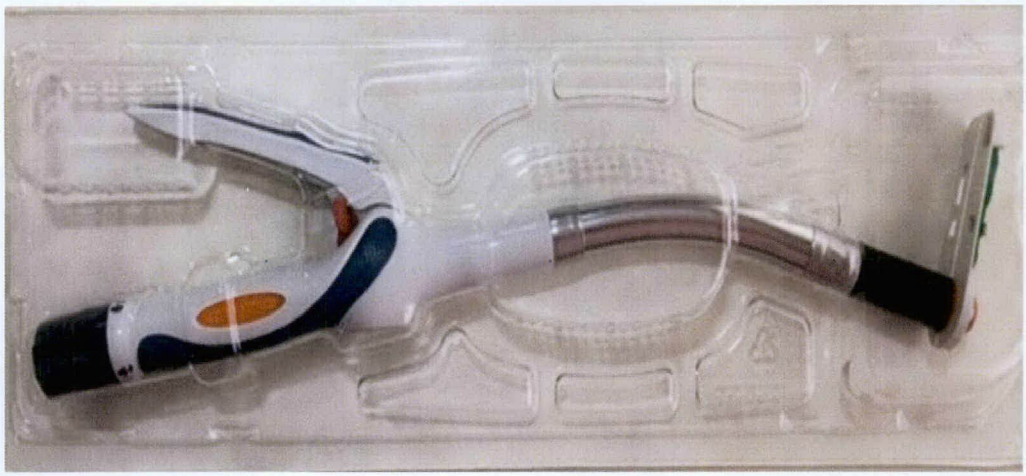

Figure 1. Proximate ILS Curved Intraluminal Stapler for recall

Through investigation of complaints and returned products, Ethicon has confirmed occurrence of uncut washers and malformed staples with the above mentioned medical device, which can compromise staple line integrity. If a problem with the staple line is not adequately addressed or is not recognized, there is a potential risk of postoperative anastomotic leak, gastrointestinal injury, hemorrhage, or hemorrhagic shock.

Based on Ethicon's analysis of complaints received to date and estimated device usage, the predicted occurrence of complaints for malformed staples has increased but is expected to remain below 0.1%. Ethicon is implementing corrective actions to resolve the shift in product performance.

In light of the foregoing, all concerned healthcare professional, establishment, and the general public is warned to discontinue further use, sale, and distribution of the above mentioned medical device.

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.

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

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) 857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
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