Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

16 OCT 2020

FDA ADVISORY
No. 2020-309-A

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

SUBJECT: **Termination of the Voluntary Product Recall of Cardinal Health™ Non-Reinforced Surgical Gown as Stated in the FDA Advisory No. 2020-309**

This is to inform the public and concerned healthcare professionals that the Voluntary recall order issued on specific lots of Cardinal Health™ Non-Reinforced Surgical Gown as shown in the table below is hereby terminated by the Food and Drug Administration (FDA).

Product Name	Product Code	Item Description	Lot Number
Cardinal Health™ Non-Reinforced Surgical Gown	ASG9515	AAMI 3 NON-REINF SURGICAL GOWN LG 2 TWL	XXXXJXXX
	ASG9545	AAMI 3 NON-REINF SURGICAL GOWN XL 2 TWL	

As stated in the FDA Advisory No. 2020-309 dated 10 March 2020, Lifelink, Inc. has conducted the voluntary recall of the aforementioned product due to the field safety notice from their supplier, Cardinal Health. The affected gowns were manufactured in the location that did not maintain proper environmental conditions as required by US law. Also, they were not registered with the US FDA. Further, the said products lacked requisite qualifications by Cardinal Health. Lastly, they were commingled with properly manufactured gowns. As a result, Cardinal Health cannot provide assurances that the identified item codes and lot numbers were properly sterilized. An improperly sterilized surgical gown could compromise a sterile field and increase the risk of a surgical site infection.

After due and thorough evaluation of the submitted documents by Lifelink, Inc., FDA has determined that reasonable efforts had been made to recall the affected product batch/lot in accordance with FDA Circular No. 2016-012, known as the Guidelines on Product Recall.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be subsequent findings of any violation of existing FDA laws, rules and regulations.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to monitor and seize the cited products batches/lots if still found available in the market.

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

Dissemination of this advisory to all concerned is hereby requested

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Director General

DTN 20200128091444