Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-309

10 MAR 2020

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of Cardinal Health™ Non-Reinforced Surgical Gown**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Cardinal Health™ Non-Reinforced Surgical Gown, manufactured by Cardinal Health, imported and distributed by Lifelink, Inc.:

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	

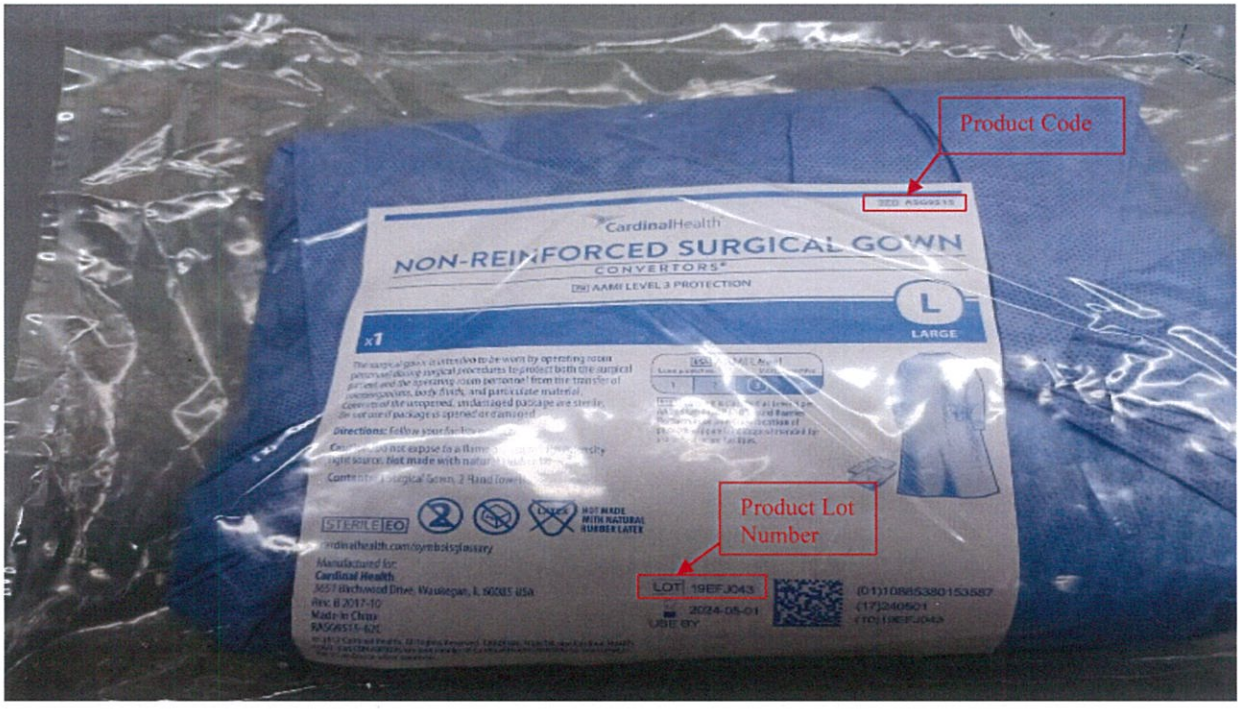

Figure 1. Cardinal Health™ Non-Reinforced Surgical Gown for recall

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 at location that did not maintain proper environmental conditions as required by US law, were not registered with the US FDA, were not qualified by Cardinal Health and 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. **The affected gowns were distributed between 1 September 2018 and 10 January 2020.** In order to determine the date of manufacture, refer to the lot number formatting below:

Single-Sterile Lot Format: YYMRJXXX
Where:
YY – Last two digits of the year ('18 or '19)
M – Month in alpha code • If made in 2018 – o "J" for September o "K" for October o "L" for November OR o "M" for December • If made in 2019, any value is affected
R – Product revision or suffix
P – Facility code is letter "J"
XXX Sequential Number – Monthly reset

Note: Gowns manufactured prior to 2018 are not affected by this recall.

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 said 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.

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DTN 20200128091444