Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

13 FEB 2020

FDA ADVISORY
No. 2020-157

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

SUBJECT: **Voluntary Recall of Unisepta® Foam 2 Medical Device Disinfectant 750ml**

The Food and Drug Administration (FDA) warns all healthcare professional and the general public on the voluntary recall of Unisepta® Foam 2 Medical Device Disinfectant 750ml with MDR No. 06986, imported and distributed by Dental Domain:

Product Name	Lot Number
Unisepta® Foam 2 Medical Device Disinfectant 750ml	A08702S
	A21511S
	A31010S
	B10630S

Figure 1. Unisepta® Foam 2 Medical Device Disinfectant 750ml for recall

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Dental Domain has conducted the voluntary recall of the aforementioned product due to the announcement from their supplier, USF Healthcare. According to their supplier, a contamination with gram negative bacteria Burkholderia Capacia commonly found in water has been identified in the manufacturing process of the affected products at their subcontractor. The bacteria pose little medical risk to healthy people. However, immunocompromised patients are at higher risk of infection. They have moved to test their products to ensure the safety and decontamination of the manufacturing facilities has been done.

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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