Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-1382-A

02 MAR 2021

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

SUBJECT: **Termination of the Voluntary Recall of Jamshidi™ Bone Marrow Biopsy / Aspiration Needle, with Luer-Lock Adapter 11GX4 ASP as Stated in the FDA Advisory No. 2020-1382**

This is to inform the public and concerned healthcare professionals that the Voluntary Recall order issued on specific lots of Jamshidi™ Bone Marrow Biopsy / Aspiration Needle, with Luer-Lock Adapter 11GX4 ASP as shown in the table below is hereby terminated by the Food and Drug Administration (FDA).

Product Name	Product Code	Lot Number
Jamshidi™ Bone Marrow Biopsy / Aspiration Needle, with Luer-Lock Adapter 11GX4 ASP	DJ4011X	0001303256
		0001303257

As stated in the FDA Advisory No. 2020-1382 dated 20 July 2020, Lifelink Inc. has conducted the voluntary recall of the aforementioned product in response to the information provided by their supplier, Becton, Dickinson and Company (BD). According to their supplier, the affected medical device product listed in the table above maybe at risk of having some packaging pouches that was not sealed properly. When used, the improperly sealed medical device product may introduce contaminants or disease vectors into the patient's body which may lead to contamination or infection.

After due and thorough evaluation of the submitted documents by Lifelink Inc., FDA has determined that reasonable efforts have been made to recall and properly destroy the affected product lots 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 product 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

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