Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20201382

20 JUL 2020

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

SUBJECT: **Voluntary Recall of "Jamshidi™ Bone Marrow Biopsy/Aspiration Needle, with Luer-Lock Adapter 11GX4 ASP"**

The Food and Drug Administration (FDA) warns all healthcare professional and the general public on the voluntary recall of Jamshidi™ Bone Marrow Biopsy/Aspiration Needle, with Luer-Lock Adapter 11GX4 ASP with MDR No. 04161, manufactured by CareFusion DR 203 Ltd. and distributed by Lifelink Inc.:

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

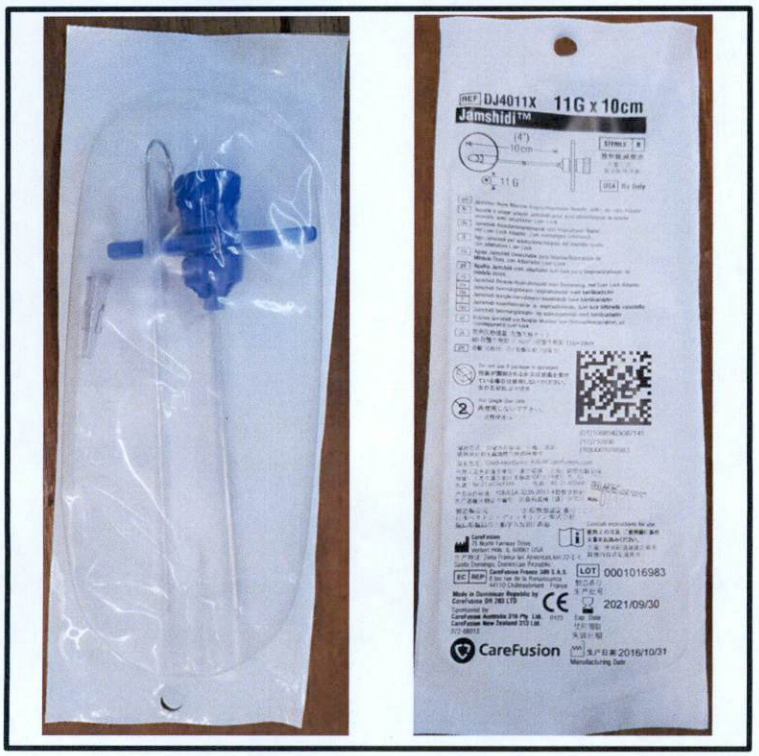

Figure 1. Jamshidi™ Bone Marrow Biopsy/Aspiration Needle, with Luer-Lock Adapter 11GX4 ASP for recall

Lifelink Inc. received a letter from Becton, Dickinson and Company (BD) informing that the product code and lot number combination of the affected medical device product listed in the table above may be 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. At the present, there have been no reported health claims associated to the affected medical device product.

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 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) 8857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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