Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

16 JUN 2021

FDA ADVISORY
No. 2021-1317

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of BD Venflon™ Pro Safety Needle Protected I.V.Cannula**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of BD Venflon™ Pro Safety Needle Protected I.V. Cannula with FDA registration number MDR-09771 manufactured by Becton Dickinson Holdings Pte. Ltd., imported and distributed by KSM Healthcare, Inc.

Product Name	Ref/Catalog No.	Lot No.	Expiration Date
BD Venflon™ Pro Safety Needle Protected I.V. Cannula	393229	0109326	4/30/2023
	393229	9264049	9/30/2022
	393229	9281169	9/30/2022
	393224	9208914	7/31/2022

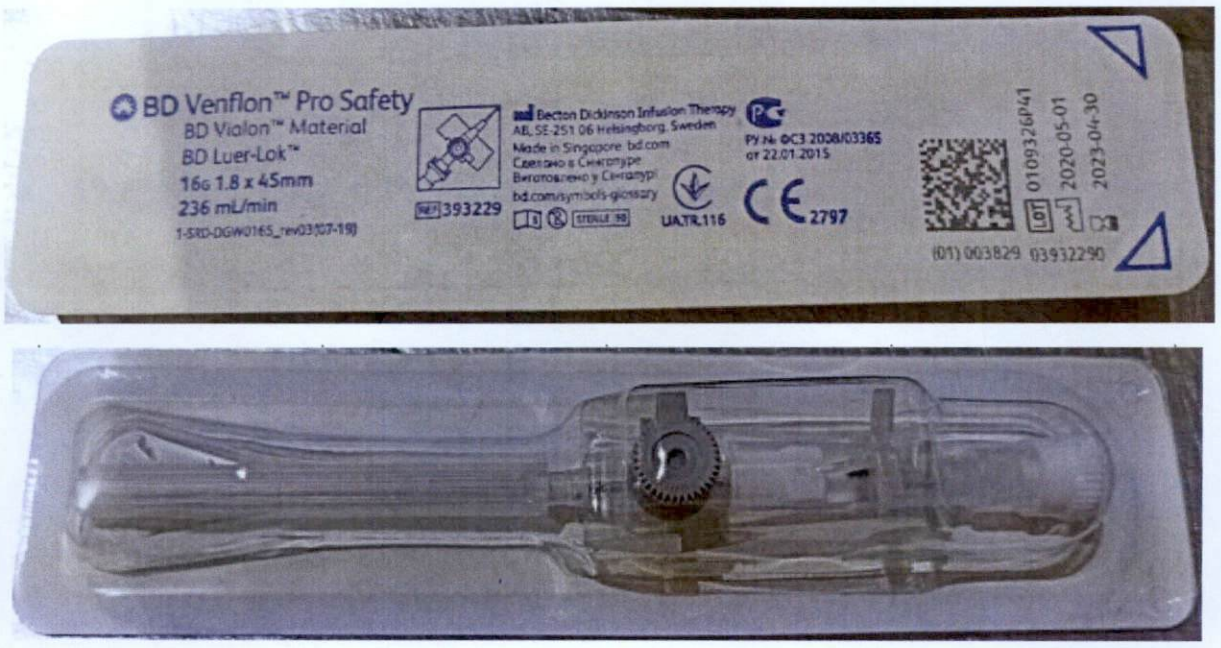

Figure 1. Photos of the affected BD Venflon™ Pro Safety Needle Protected I.V. Cannula

Based on the medical device recall notification of KSM Healthcare Inc. BD issued a Field Safety Notice (FSN) to advise users of the above-mentioned medical device that the device may exhibit leakage from the injection port. BD's ongoing post market surveillance process and after a review and further discussions with EU Regulators, BD has decided, that this FSN escalated to be a product recall of all remaining inventory of the afore stated medical device. BD is recalling all affected BD Venflon™ Pro Safety Needle Protected I.V. Cannula that has been sterilized by ethylene oxide (EtO).

Figure 2. Photos of the affected BD Venflon™ Pro Safety Needle Protected I.V. Cannula that has been sterilized by ethylene oxide (EtO)

In light of the foregoing, all concerned healthcare professional, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of BD Venflon™ Pro Safety Needle Protected I.V. Cannula

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.

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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