Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 DEC 2021

FDA ADVISORY
No. 2021-3608

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of BD Precision Glide Hypodermic Needle**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of BD Precision Glide Hypodermic Needle manufactured by Becton Dickinson Holdings Pte. Ltd., imported and distributed by KSM Healthcare, Inc.:

Product Name	Catalog Number	Lot Number
BD Precision Glide Hypodermic Needle	302006	0324712

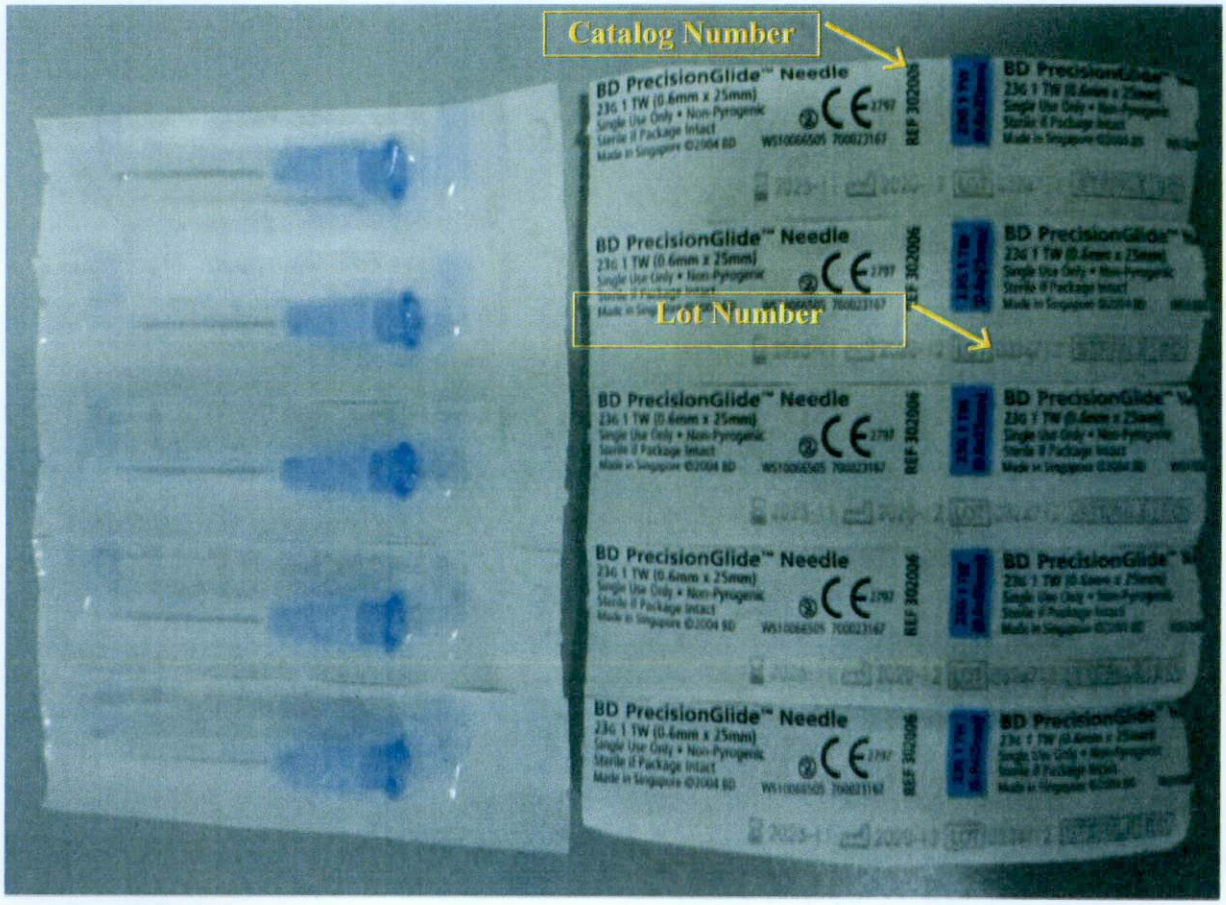

Figure 1. BD Precision Glide Hypodermic Needle

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Becton Dickinson Holdings Pte. Ltd. initiated the voluntary recall of the above-mentioned specific lots of BD Precision Glide Hypodermic Needle because of the confirmed customer reports of this product being found open and lacking adequate seals. Open seals introduce the single use needle devices to a non-sterile environment. If the issue is not identified prior to using the device, this poses an increased risk of infection to a patient that may require medical intervention, treatment and possible hospitalization. Depending on the patient population there may be risk of a life-threatening injury.

This detect is isolated to the specified Catalog and Lot Number listed in the table above. Furthermore, there have been no reports of injuries or deaths related to this recall to date.

In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots of BD Precision Glide Hypodermic Needle.

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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