Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

17 JUL 2019

FDA ADVISORY
No. 2018-297-A

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

SUBJECT: **Termination of the Voluntary Product Recall of the following medical device products:**

1. **Novosyn® Violet Dyed Suture with Needle**
2. **Safil® Violet Surgical Suture**

This is to inform the public and concerned healthcare professionals that the Voluntary recall order issued on specific batch/es of Novosyn® Violet Dyed Suture with Needle and Safil® Violet Surgical Suture as shown in the table below is hereby terminated by the Food and Drug Administration (FDA).

Article Number	Article Name	Batch
C0068029	Novosyn® Violet 4/0 (1.5) 70cm HR22 (M)	718043
		718042
		718064
C0068595	Novosyn® Violet 2/0 (3) 90cm HR 37S (M)	717526
		717525
C1048540	Safil® Violet 4/0 (1.5) 90cm HR 26 (M)	717445

As stated in the FDA Advisory No. 2018-297 dated 05 October 2018, B. Braun Medical Supplies, the Marketing Authorization Holder (MAH), conducted a voluntary recall of the above-stated medical device products as a Field Safety Corrective Action in response to the report received from the manufacturer. In the course of routine quality audits at the production site, the manufacturer detected that some units of the abovementioned batches have damaged packaging, which may have compromised the sterility of the product.

After due and thorough evaluation of the submitted documents by the MAH, FDA has determined that reasonable efforts had been made to recall and properly destroy the affected product batch 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 batches 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@fda.gov.ph**, or call **(02) 857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
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Officer-in-Charge, Director General

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