Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-297

05 OCT 2018

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

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

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

All concerned healthcare professionals and establishments are hereby advised by the Food and Drug Administration (FDA) regarding the product recall of specific batch of Novosyn® Violet Dyed Suture with Needle with MDR-00091 and Safil® Violet Surgical Suture with DVR-5893, imported and distributed by B. Braun Medical Supplies Inc.

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

B. Braun Medical Supplies is conducting a voluntary recall of the above-stated medical device product 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 above-stated manufacturing batches have damaged packaging, which may have compromised the sterility of the product. To date the company has not received market feedback on any adverse patient outcome which may be associated with the above-described observation.

All concerned healthcare professionals and establishments are advised to discontinue further use, sale and distribution of the said affected medical device product.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

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Director General

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