Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-1015

04 MAY 2022

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of Vasofix Safety IV Cannula with Injection Port (Sterile)**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected batches of Vasofix Safety IV Cannula with Injection Port (Sterile) DVR-5795 manufactured by B. Braun Melsungen AG, imported and distributed by B. Braun Medical Supplies, Inc.

Product Description	Affected Batches
Vasofix Safety IV Cannula with Injection Port (Sterile) (DVR-5795)	20C21G8346, 19L12G8345, 19L20G8345, 19L29G8330,19N09G8381, 20A07G8345 20C03G8382, 20E08G8331, 20F01G8345, 20F24G8348

Figure 1. Vasofix Safety IV Cannula with Injection Port (Sterile)

B. Braun Medical Supplies, Inc. initiated the voluntary recall of the specific batches of Vasofix Safety IV Cannula with Injection Port (Sterile) in the course of their post-market surveillance activities and identified that the injection port of the above-mentioned product might be leaky.

The defect might result in potentially critical clinical consequences for the patient such as a blood loss, underdosage or delay of therapy. The user or third parties are at risk due to contact with incompatible substances or foreign blood. Based on the identified risks and the consideration that the concerned products are mainly used for infants or in general for patients with difficult veins, we decided to proactively recall all affected devices from the market.

Furthermore, the defect is due to a production deviation starting from September 2019 onwards. The corrective action has been implemented in June 2020. All batches manufactured from July 2020 onwards are not affected.

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 batches of Vasofix Safety IV Cannula with Injection Port (Sterile).

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.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge, Director General

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