Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

13 DEC 2021

FDA ADVISORY
No. 20213486

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of Steelex Sternum Set**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Steelex Sternum Set with FDA registration number, DVR-4774, imported and distributed by B. Braun Medical Supplies, Inc.:

Product Discription	Product Registration Number
Steelex Sternum Set	DVR-4774

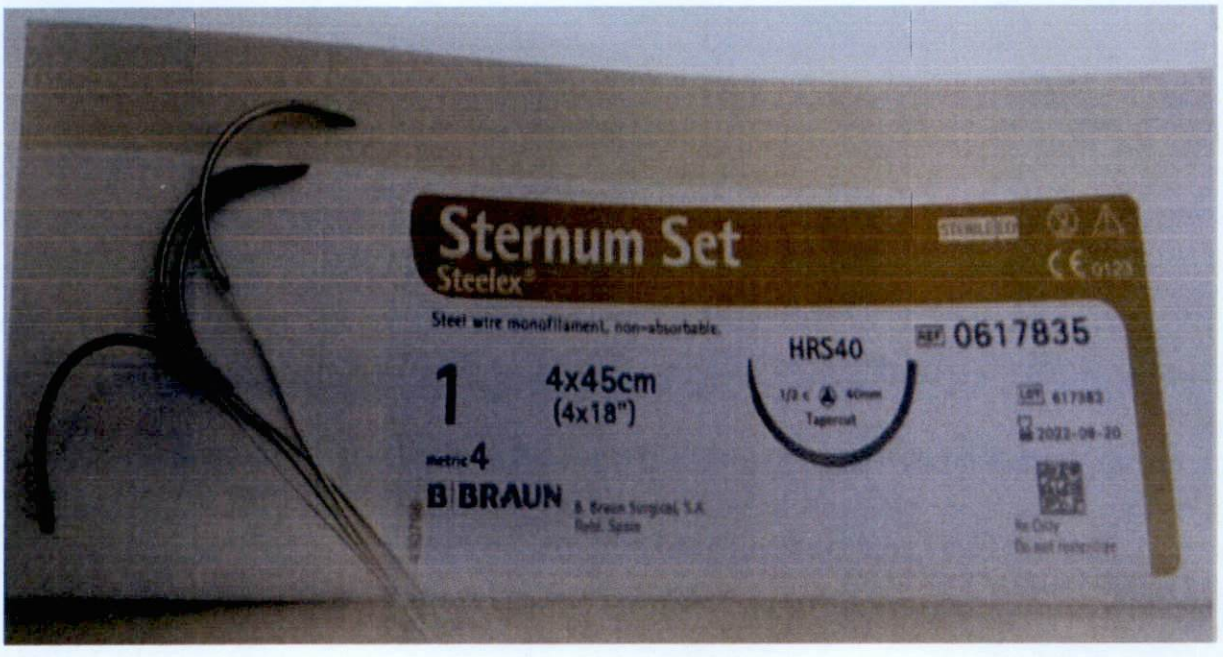

Figure 1. Steleex Sternum Set

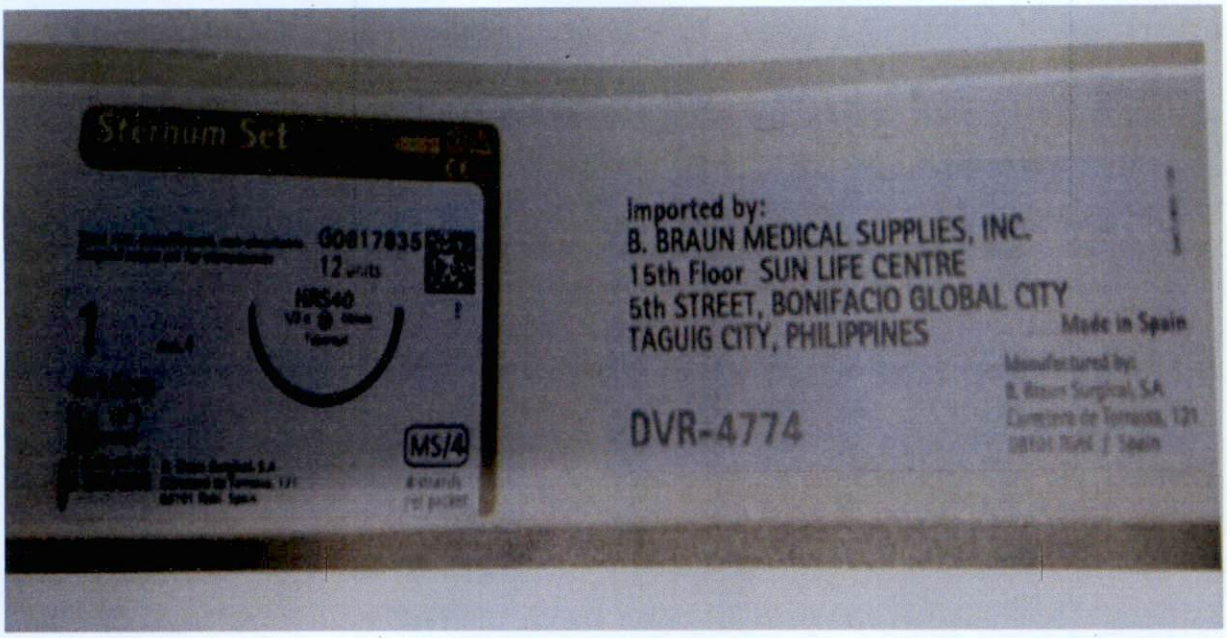

Figure 2. Steelex Sternum Set

B. Braun Medical Supplies, Inc. initiated the voluntary recall of the above-mentioned lots/batches of Steelex Sternum Set Bioburden results of Steelex Sternum Set in long Pack cardboard were determined to be out of specification, such finding was part of the Ethylene Oxide (EO) sterilization validation activities of Steelex Sternum Set.

The risk of remaining bioburden present on the cardboard inner part is considered very low as any viable bacteria should migrate from the inner part to the outer part of the sterilized support. The suture thread is made of steel a material that does not facilitate the colonization as it does not contain any component to feed bacteria. Therefore, the risk of colonization is considered low. Finally, any survival in the implantable parts could be introduced in the patient body and develop and infection. Such risk is minimized due to the antibiotic therapy applied in such cardiothoracic interventions.

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 Steelex Sternum Set.

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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