



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. 2021-3486-A

29 DEC 2021

TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS

SUBJECT: Clarification of FDA Advisory No. 2021-3486 "Voluntary Product Recall of Steelex Sternum Set"

The Food and Drug Administration (FDA) clarifies that only the following affected Lots and Batches of Steelex Sternum Set are being voluntarily recalled by B. Braun Medical Supplies, Inc.:

PRODUCT DESCRIPTION	AFFECTED LOTS	AFFECTED BATCHES
Steelex Sternum Set Product registration number: DVR-4774	G0617135	616381V110, 616392V110, 616405V110, 616443V110, 617421V110, 617431V110, 618381V110
	G0617134	616426V110, 616505V110, 617241V110, 617263V110, 617496V110, 617505V110, 618011V110
	G0617733	616471V110, 617221V110
	G0617742	616507V110
	G0617806	617032V110, 618011V110
	G0617741	617163V110, 617212V110, 617334V110, 617462V110, 617471V110, 618062V110, 618092V110
	G0617835	617383V110, 617432V110, 619436V110, 620312V110, 620431V110
	G0617796	617473V110, 617496V110, 619091V110

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/batches of Steelex Sternum Set.

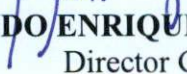


All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lots/batches 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 cdrhr@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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