Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

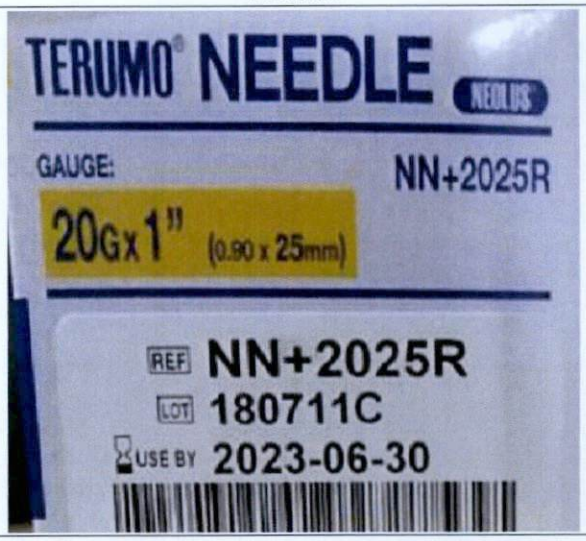
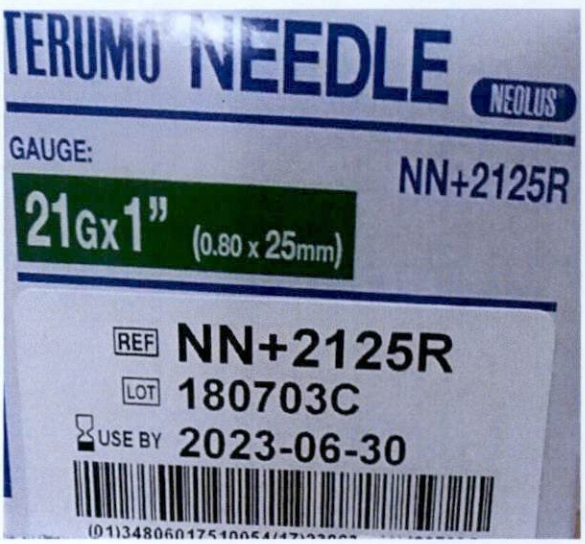
FDA ADVISORY
No. 20201600

03 SEP 2020

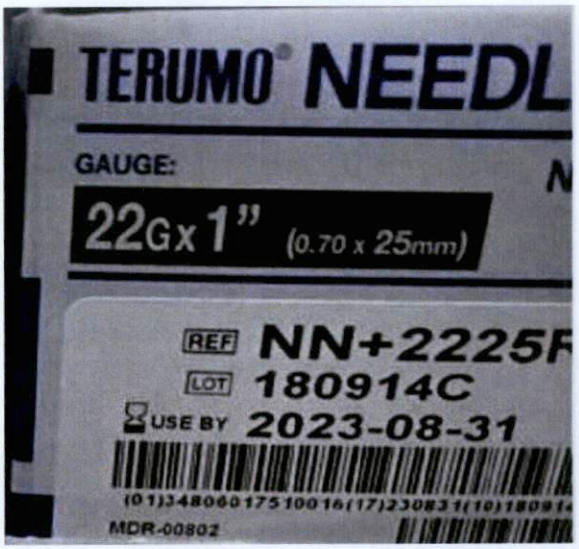
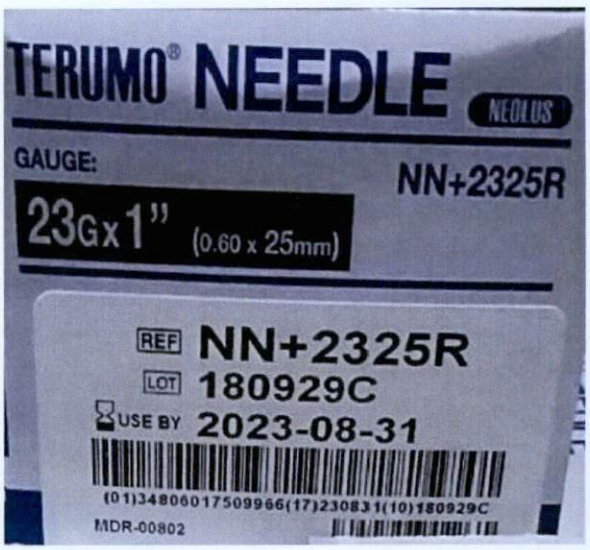
TO: **THE GENERAL PUBLIC AND ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

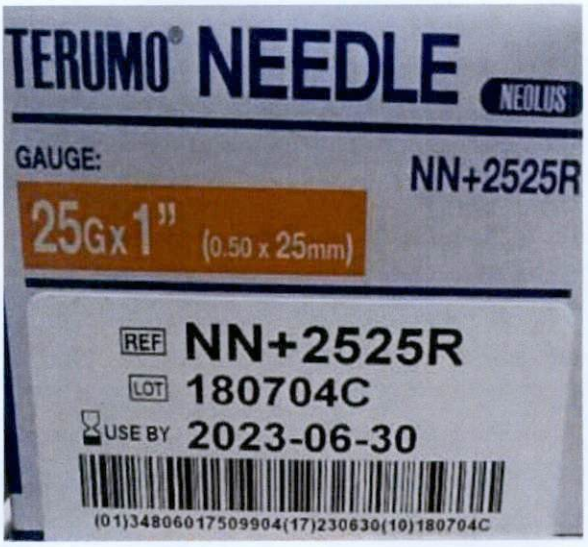
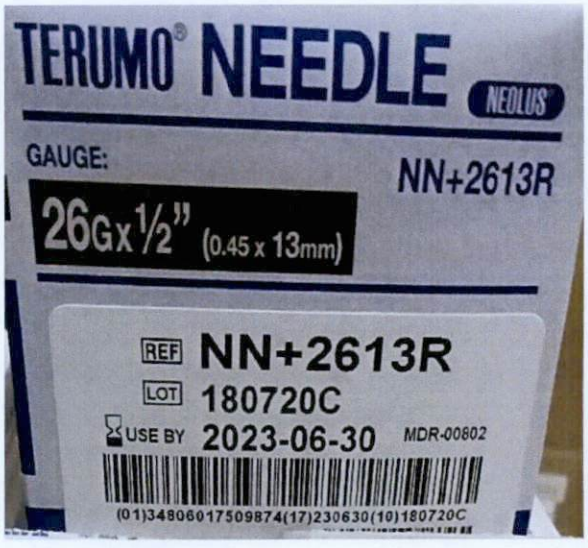
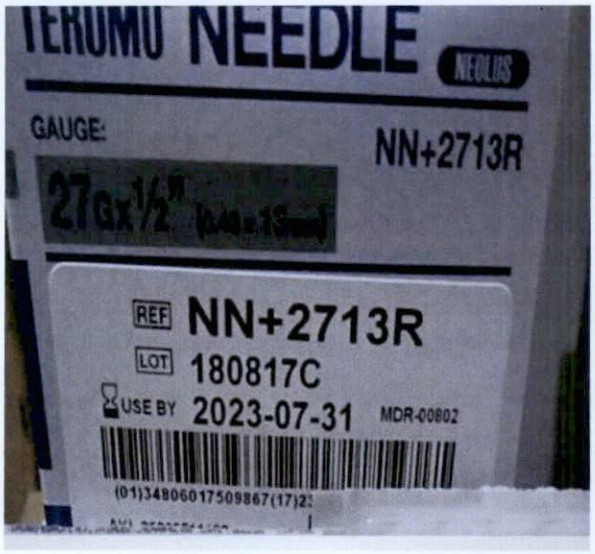
SUBJECT: **Termination of the Voluntary Product Recall of Terumo® Needle**

This is to inform the public and concerned healthcare professionals that the Voluntary recall order issued on selected lots of Terumo® Needle with MDR No. 00802 manufactured by Terumo Philippines Corporation, as shown in the table below is hereby terminated by the Food and Drug Administration (FDA).

Item Code	Lot Number	Picture
NN+2025R	180711C 180831C	
NN+2125R	180703C 180910C 181011C	

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

Item Code	Lot Number	Picture
NN+2225R	180810C 180914C 181005C	
NN+2325R	180707C 180917C 180929C	
NN+2425R	180719C 180910C	

Item Code	Lot Number	Picture
NN+2516R NN+2525R	180703C 180929C 180704C 181018C	
NN+2613R	180703C 180720C 180802C 180911C 181018C	
NN+2713R	180817C 180822C 180907C	

As stated in the FDA Advisory No. 2019-079 dated 15 March 2019, Terumo Marketing Philippines Inc. received a customer complaint that the blister seals of the above-mentioned medical device are narrows or misaligned. After the investigation, it was observed that the sealing portion (width) of the blister package was below the manufacturing standard of 1.5mm and a small opening on the package resulting to seal breach. The reason for recall is the potential loss of packaging integrity that may compromise the sterility of the subject medical device product.

After due and thorough evaluation of the submitted documents by Terumo Marketing Philippines Inc., 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 lots 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) 8857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20190129164830