Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

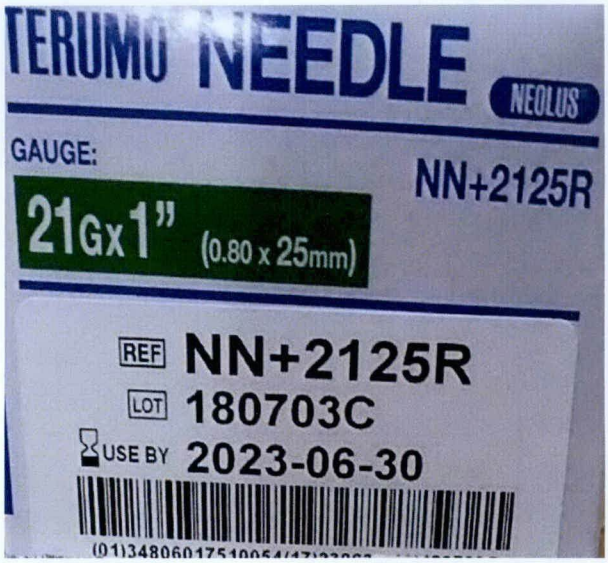
FDA ADVISORY
No. 2019-079

15 MAR 2019

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

SUBJECT: **Voluntary Recall of Terumo® Needle**

All concerned healthcare professionals and establishments are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary product recall of selected lots of Terumo® Needle with MDR No. 00802 (see photos of the affected product below), manufactured by Terumo Philippines Corporation.

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

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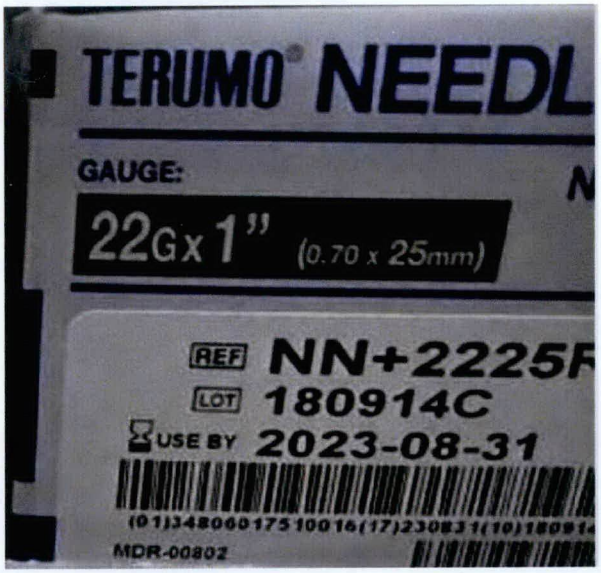
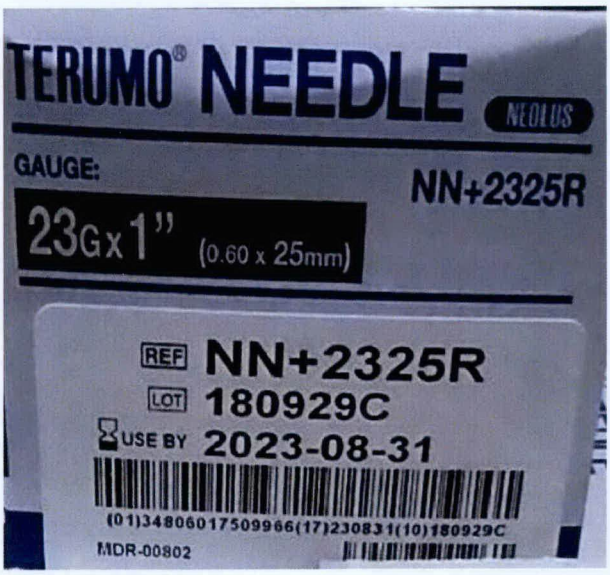
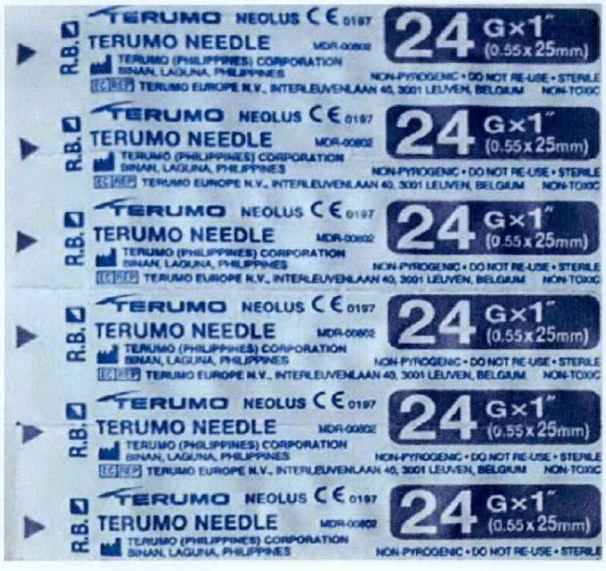
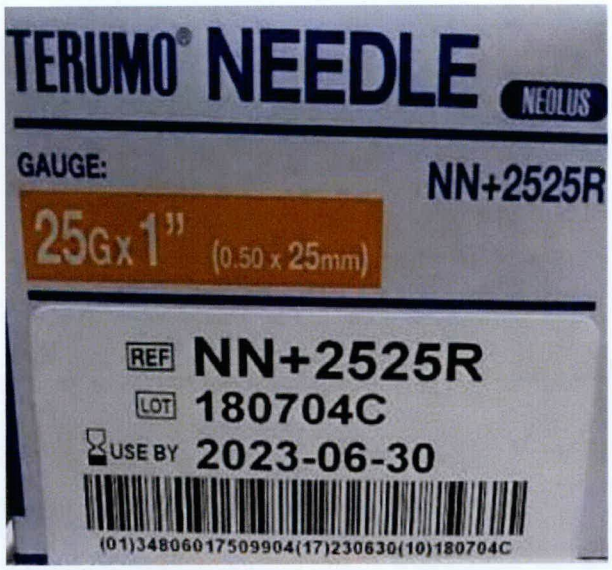
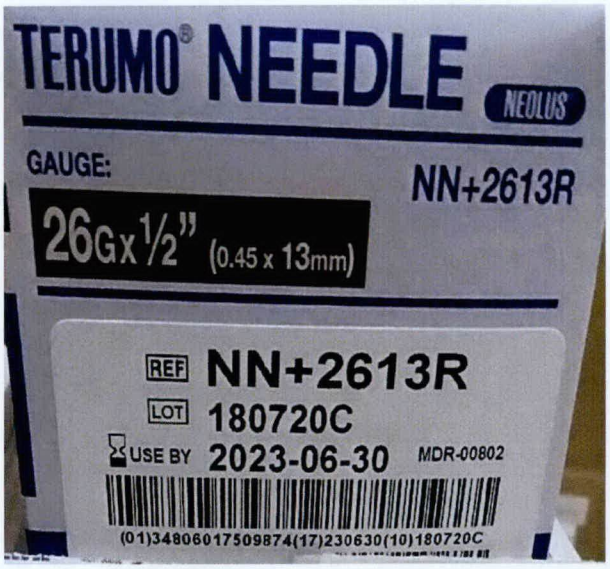
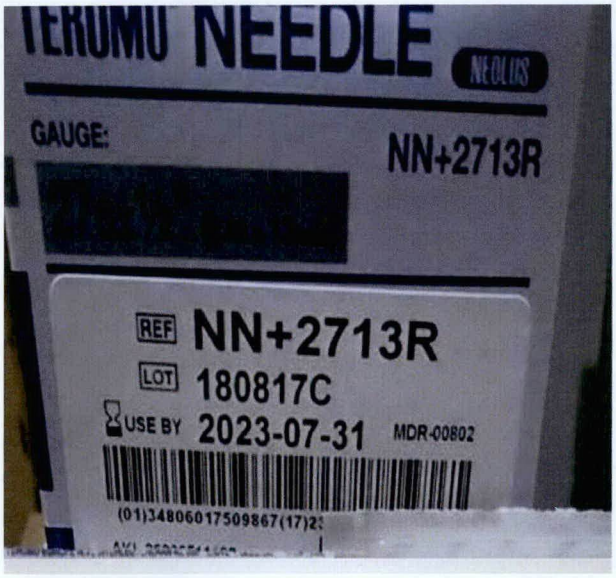
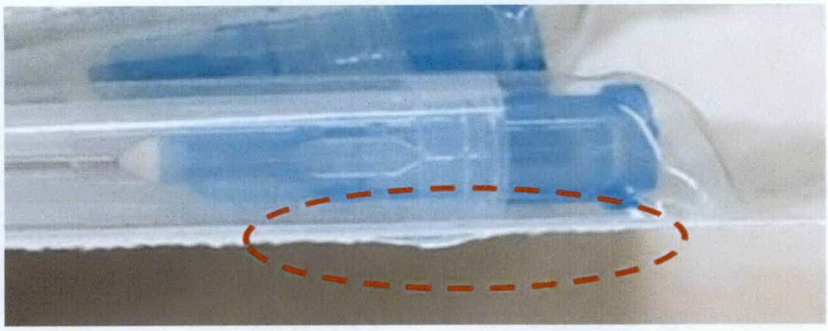
Item Code	Lot Number	Picture
NN+2225R	180810C 180914C 181005C	
NN+2325R	180707C 180917C 180929C	
NN+2425R	180719C 180910C	

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	

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 was observed (see image below).



The reason for recall is the potential loss of packaging integrity that may compromise the sterility of the subject medical device product. There have been no reported patient injuries associated to this issue.

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 cdrrhrprsdd@yahoo.com 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.

NELA CHARADE G. PUNO, RPh
Director General

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