Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-1124-A

08 SEP 2021

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

SUBJECT: **Completion of the Voluntary Recall of Covidien Surgiwand™ II Suction and Irrigation Devices**

This is to inform all concerned healthcare professionals and establishments that the Voluntary Recall of affected lots/batches of Covidien Surgiwand™ II Suction and Irrigation Devices, manufactured by Covidien-USA and imported by Medtronic Philippines, Inc. as shown in the table below is completed and hereby closed by the Food and Drug Administration (FDA).

Item Code	Description	Affected Lot Numbers			
178093	Surgiwand™ II Auto Suture™ Suction and Irrigation Device with L-Hook Tip 5 mm	P9E1279Y	P0F0440Y	P9C1632Y	P0F0441Y

As stated in the FDA Advisory No. 2021-1124 dated 21 May 2021, Medtronic Philippines, Inc. has conducted the voluntary recall of the aforementioned product due to reported foreign particles in the device tubing. Based on the investigation of their manufacturer, they identified an assembly process that could potentially damage the "Y-connector," allowing for small pieces of the connector to move through the device tubing. Use of this device with this issue may result in infection, allergic reaction. Manufacturing process improvement have been implemented to remediate this issue. There have been no reports of serious injury to this issue.

After due and thorough evaluation of the submitted documents by Medtronic Philippines, Inc., FDA has determined that reasonable efforts have been made to recall and properly returned to the source country the affected product batches 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.

TÜVRheinland CERTIFIED Management System ISO 9001:2015 www.tuv.com ID 9105073396

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at cdrrhr-prsdd@fda.gov.ph, or call (02) 8857-1900 local 8301.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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