



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



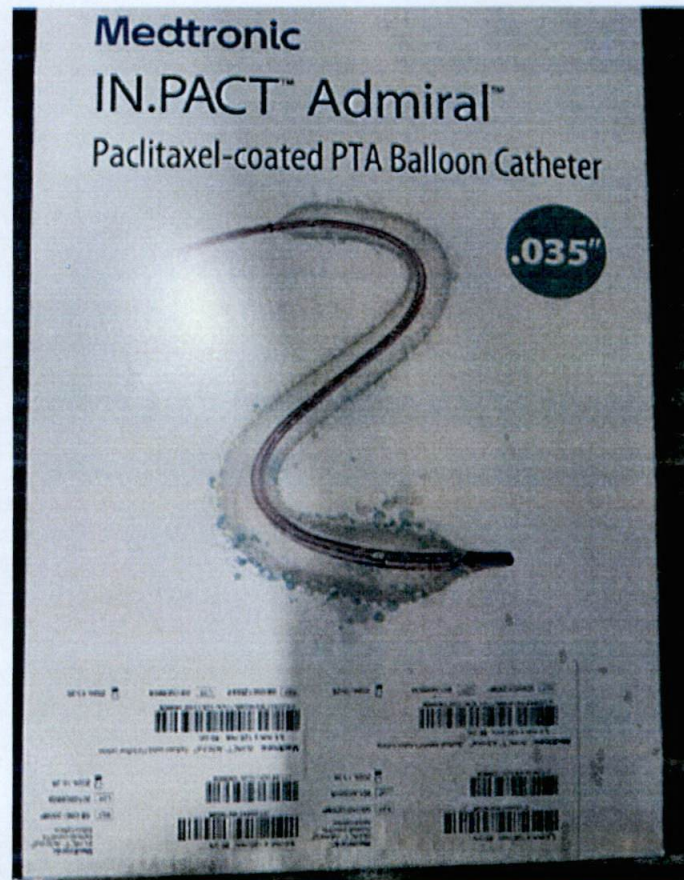
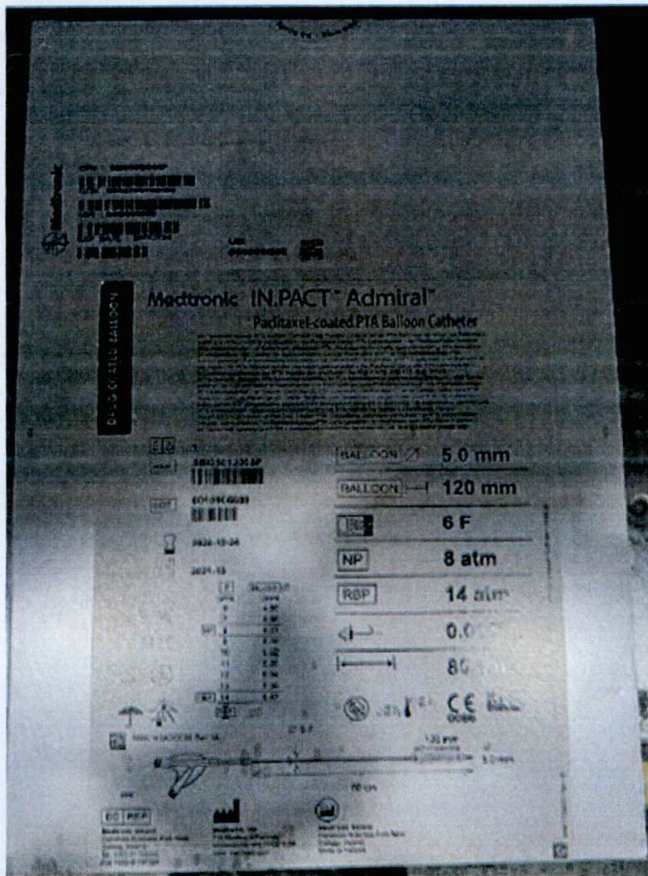
07 DEC 2022

FDA ADVISORY
No. **2022-2056**

TO: ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS

SUBJECT: Termination of the Voluntary Recall of IN.PACT™ ADMIRAL PACLITAXEL-ELUTING PTA BALLOON CATHETER as stated in the FDA Advisory No. 2022-1526

This is to inform all concerned healthcare professionals and establishments that the Voluntary Recall of affected lots/batches of IN.PACT™ ADMIRAL PACLITAXEL-ELUTING PTA BALLOON CATHETER with FDA Registration Number MDR-01748 manufactured by Medtronic International Ltd., imported and distributed by Medtronic Philippines, Inc. as shown below is completed and hereby closed by the Food and Drug Administration (FDA).



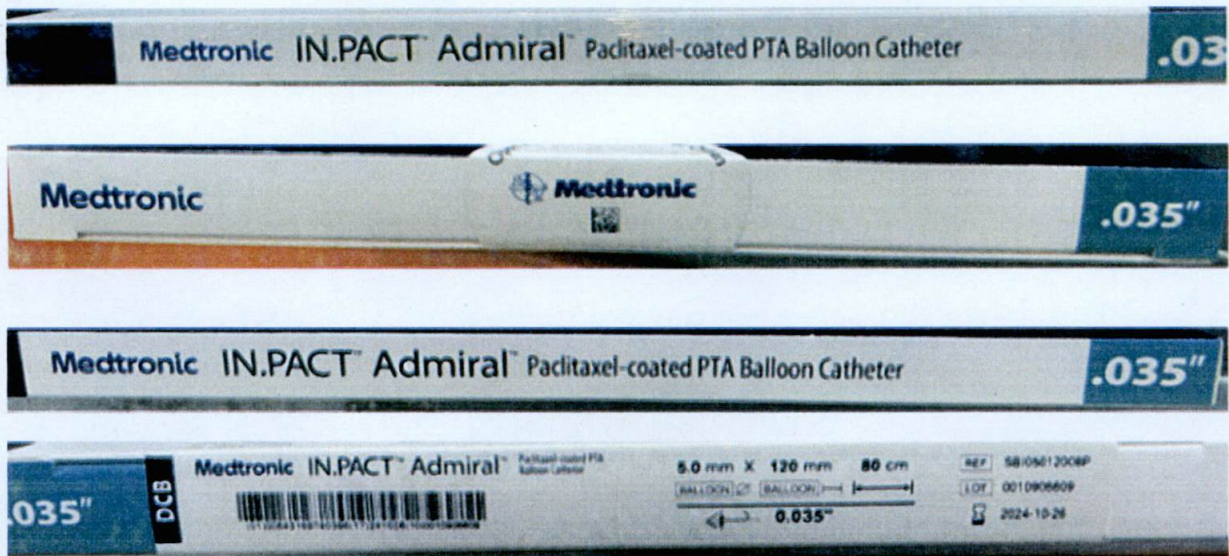


Figure 1. IN.PACT™ ADMIRAL PACLITAXEL-ELUTING PTA BALLOON CATHETER

As stated in the FDA Advisory No. 2022-1526 dated 01 September 2022, Medtronic Philippines, Inc. has conducted the voluntary recall of the aforementioned product in response to due to the potential for pouch damage resulting in potential loss of sterility.

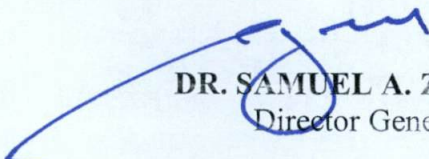
After due and thorough evaluation of the submitted documents by Medtronic Philippines, Inc., FDA has determined that reasonable efforts have been made to recall and properly returned to the source country the affected product batches in accordance with FDA Circular No. 2016-012, known as the Guidelines 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.

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

Dissemination of this advisory to all concerned is hereby requested.


DR. SAMUEL A. ZACATE
Director General

DTN 20220426134008