



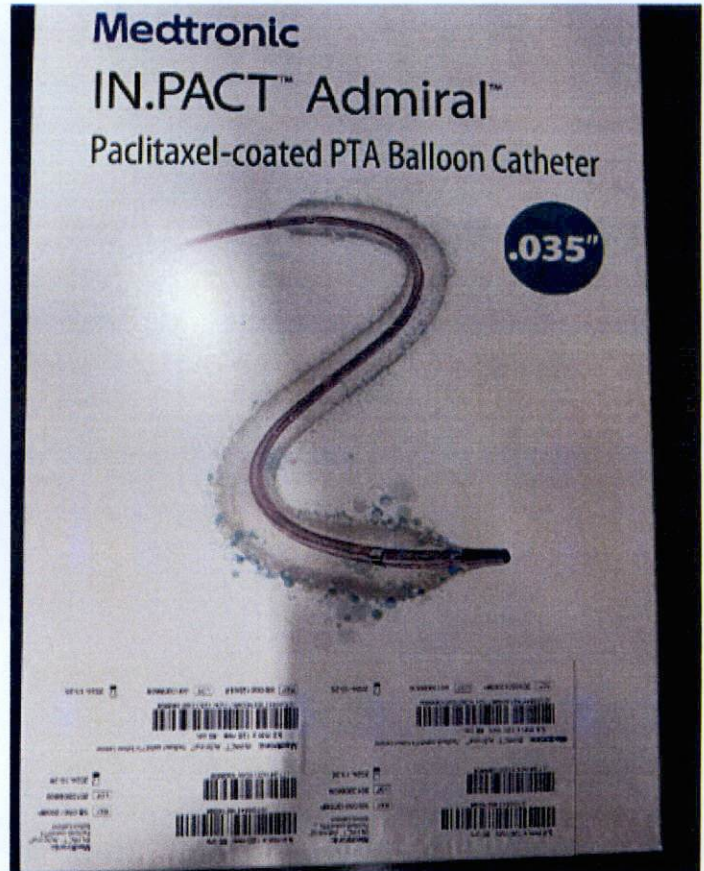
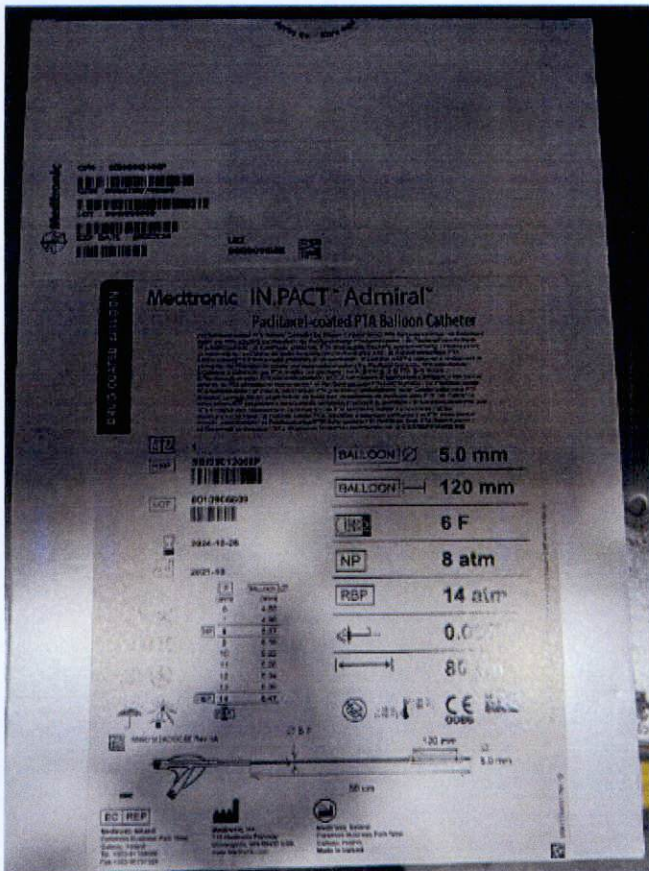
FDA ADVISORY
No. **2022-1526**

01 SEP 2022

TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS

SUBJECT: Voluntary Recall of IN.PACT™ Admiral™ and IN.PACT™ AV Paclitaxel-coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheters

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall 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.



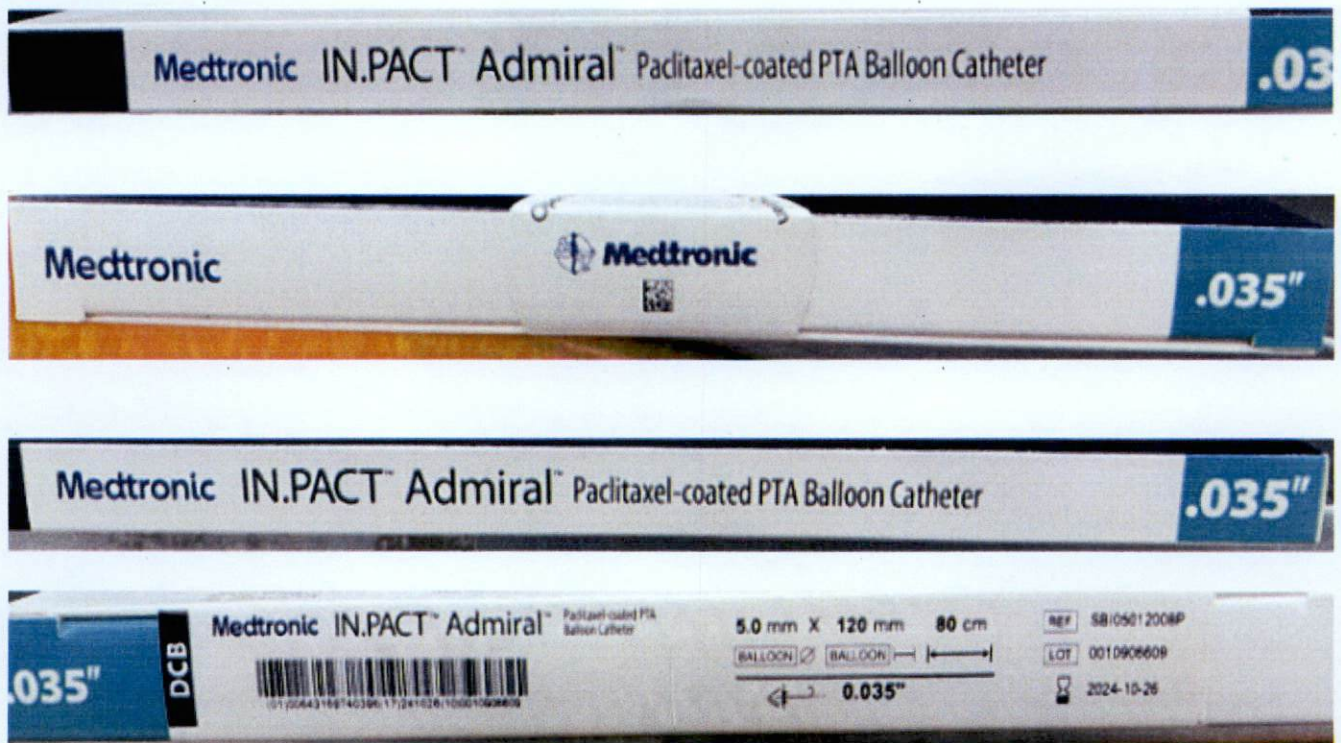


Figure 1. IN.PACT™ ADMIRAL PACLITAXEL-ELUTING PTA BALLOON CATHETER

Medtronic Philippines, Inc. initiated the voluntary recall the subset of IN.PACT™ Admiral™ and IN.PACT™ AV Paclitaxel-coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheters due to the potential for pouch damage resulting in potential loss of sterility.

According to Medtronic Philippines, Inc., the registered “IN.PACT™ Admiral™”, is the only affected product involved in the voluntary recall. In addition, no additional actions were required for the affected product.

In light of the foregoing, all concerned healthcare professional, establishments, and the general public are warned to discontinue further use, sale, and distribution of the product IN.PACT™ ADMIRAL PACLITAXEL-ELUTING PTA BALLOON CATHETER.

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 lot numbers 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 cdrrhr@fda.gov.ph, or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.



DR. SAMUEL A. ZACARTE
Director General

DTN 20220426134008