Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-1533

01 SEP 2022

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

SUBJECT: **Completion of the Voluntary Recall of Hurricane™ RX Biliary Balloon Dilatation Catheter**

This is to inform all concerned healthcare professionals and establishments that the Voluntary Recall of affected lots/batches of Hurricane™ RX Biliary Balloon Dilatation Catheter manufactured by Boston Scientific Limited and imported by Boston Scientific Philippines, Inc. as shown in the table below is completed and hereby closed by the Food and Drug Administration (FDA).

Product Description	Material / Reference No.	Lot / Batch
Hurricane™ RX Biliary Balloon Dilatation Catheter 8MM 4CM	M00545940	26473775, 27110099, 26406534
Hurricane™ RX Biliary Balloon Dilatation Catheter 10MM 4CM	M00545960	27065900, 26677002, 26651709
Hurricane™ RX Biliary Balloon Dilatation Catheter 6MM 4CM	M00545920	27100240
Hurricane™ RX Biliary Balloon Dilatation Catheter 4MM 4CM	M00545900	26087729, 26087720, 26240367, 26207977

As stated in the FDA Advisory No. 2022-1021 dated 04 April 2022, Boston Scientific Philippines, Inc. has conducted the voluntary recall of the aforementioned product in response to an increase of complaints reported for pinholes in the balloon. The user may notice that the balloon either rapidly loses pressure or fails to gain or maintain pressure. The most common potential consequence that is reasonably foreseeable to occur is a prolonged procedure while the device is exchanged. If a prolonged procedure were to occur, it is not anticipated to result in a clinically significant delay in the procedure. Furthermore, there have been no reports of injuries related to this recall to date.

After due and thorough evaluation of the submitted documents by Boston Scientific 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 cdrrhr-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

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