0 4 APR 2022

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20221021

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TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

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

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of the following affected lots/batches of Hurricane™ RX Biliary Balloon Dilatation Catheter manufactured by Boston Scientific Limited located in Cork, Ireland, imported and distributed by Boston Scientific Philippines:

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

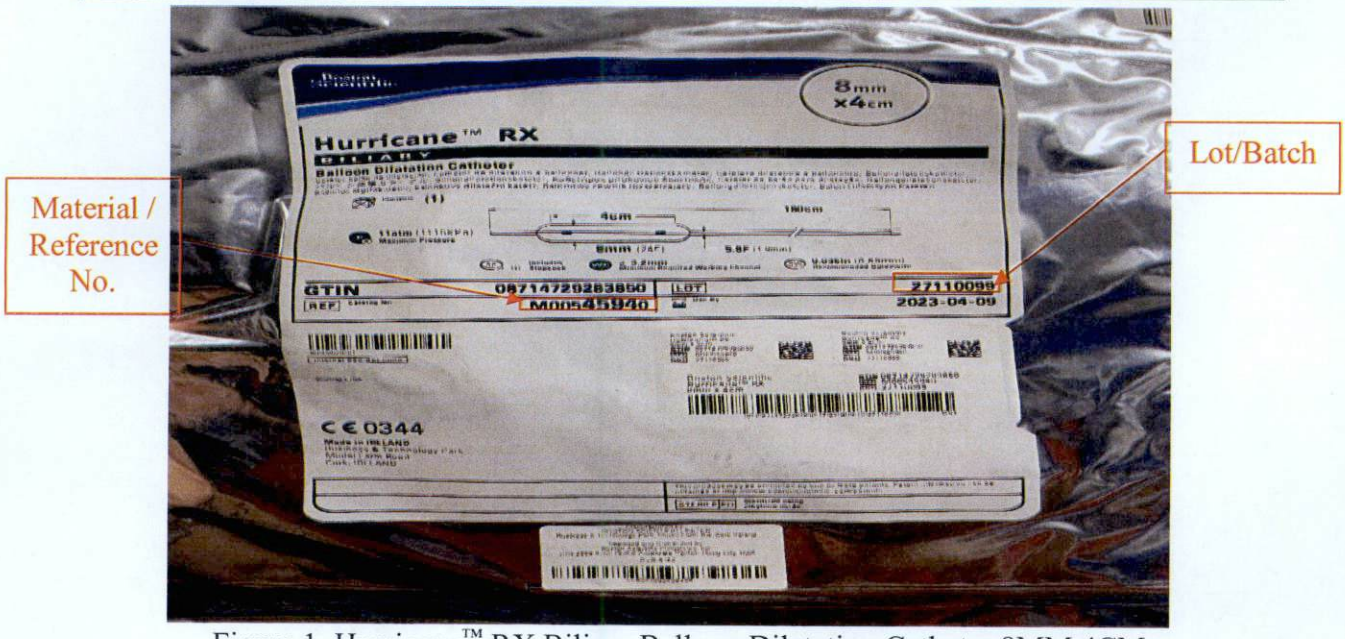

Figure 1. Hurricane™ RX Biliary Balloon Dilatation Catheter 8MM 4CM

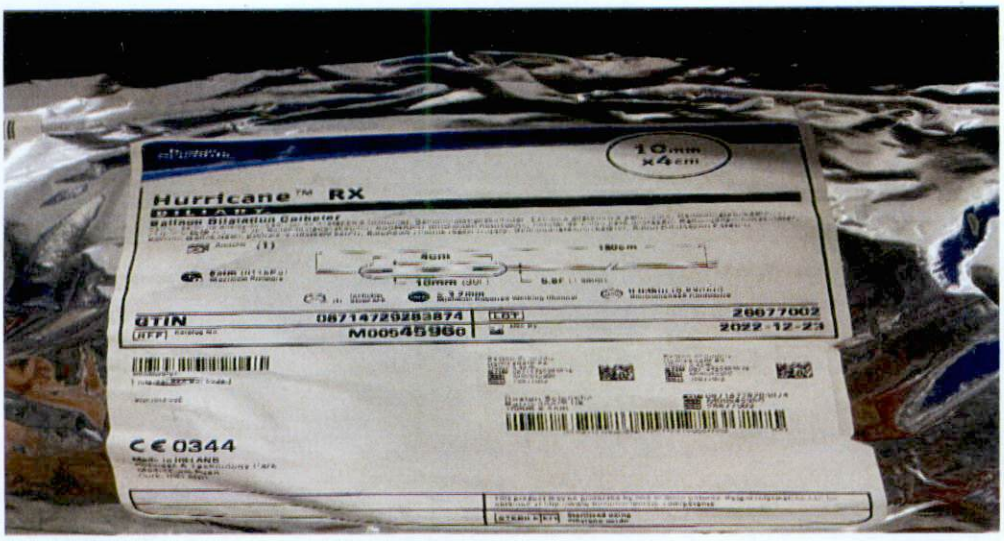

Figure 2. Hurricane™ RX Biliary Balloon Dilatation Catheter 10MM 4CM

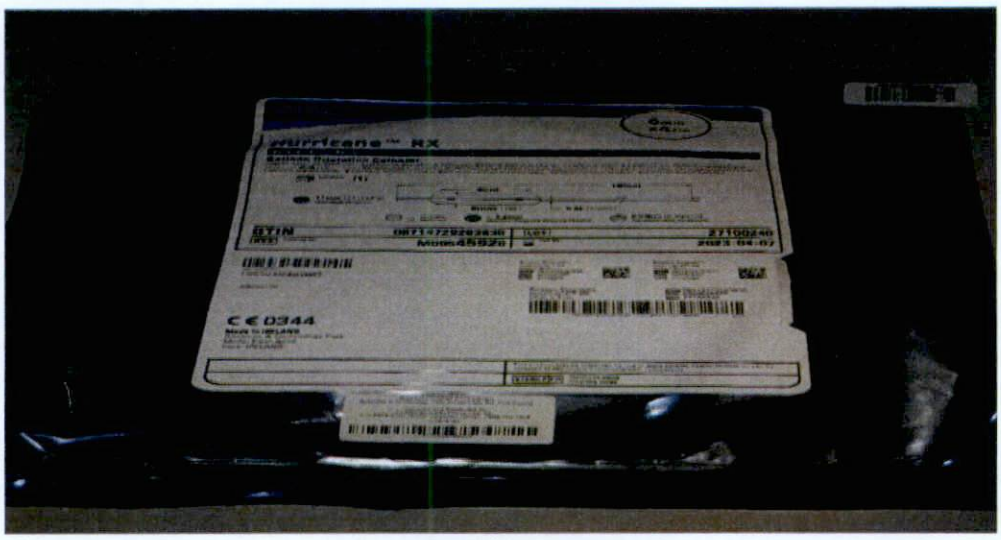

Figure 3. Hurricane™ RX Biliary Balloon Dilatation Catheter 6MM 4CM

Figure 4. Hurricane™ RX Biliary Balloon Dilatation Catheter 4MM 4CM

Boston Scientific Corporation initiated the voluntary recall of the above-mentioned specific lots/batches of Hurricane™ RX Biliary Balloon Dilatation Catheter 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 which is the most serious 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.

In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of Hurricane™ RX Biliary Balloon Dilatation 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/batch 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. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN 20220218164416