Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-045

14 FEB 2018

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

SUBJECT: **Voluntary Product Recall of Guider Softip Guiding Catheter**

All concerned healthcare professionals and establishments are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary product recall of specific lots of Guider Softip Guiding Catheter with DVR No. 4230 (see photos of the product below), distributed and imported by Partners' Choicemed, Inc.

DESCRIPTION	LOT NO.
GUIDER/ 40 DEG XF /7FR/ 9CM	19793264
	18056772
	20013730
	20601623
	17987235
	17997088
	19791829
	20471803
	18056695
	19787277
	20144784
	20601934
	18116710
	20471804

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

DESCRIPTION	LOT NO.
GUIDER/ 40 XF /8F/ 90CM	19157528 19159673

Partners' Choicemed, Inc. received a notice of product recall from Stryker Neurovascular, in coordination with Boston Scientific the manufacturer of the above-mentioned medical device product. Stryker Neurovascular has become aware that the above-mentioned lots of Guider 7F and 8F product may be at risk of degrading within its shelf-life period. The root cause of the issue is exposure of components to UV light while in storage between 2014 and October 2017. Patients previously treated with the impacted devices are not at risk. For potential patients, the reported issue can cause the embolization of degraded polymer fragments into the neurovasculature which can cause stroke. There have been no reports of catheter degradation or injury.

All concerned healthcare professionals and establishments are advised to discontinue further use, sale and distribution of the said affected medical device product.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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