Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

05 OCT 2020

FDA ADVISORY
No. 20201811

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the following Unregistered Medical Device Products:**

1. **Polaris™ Loop – Dual Durometer Percuflex™ Material - Ureteral Stent (Product No. M0061552440)**
2. **Contour VL™ – Soft Percuflex™ Material – Variable Length Ureteral Stent (Product No. M0061801570)**
3. **Percuflex™ Plus - Ureteral Stent (Product No. M0061752520)**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the following unregistered medical device products:

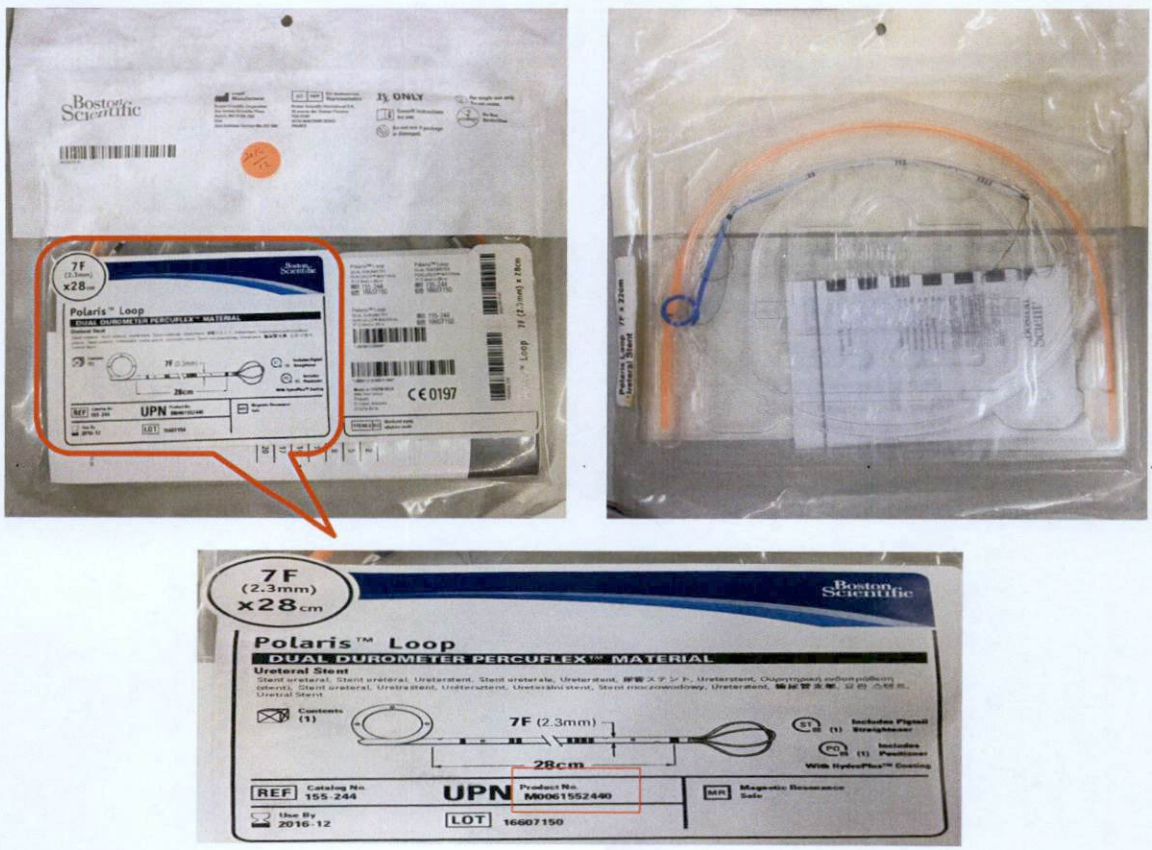

Figure 1. Unregistered Polaris™ Loop – Dual Durometer Percuflex™ Material – Ureteral Stent (Product No. M0061552440)

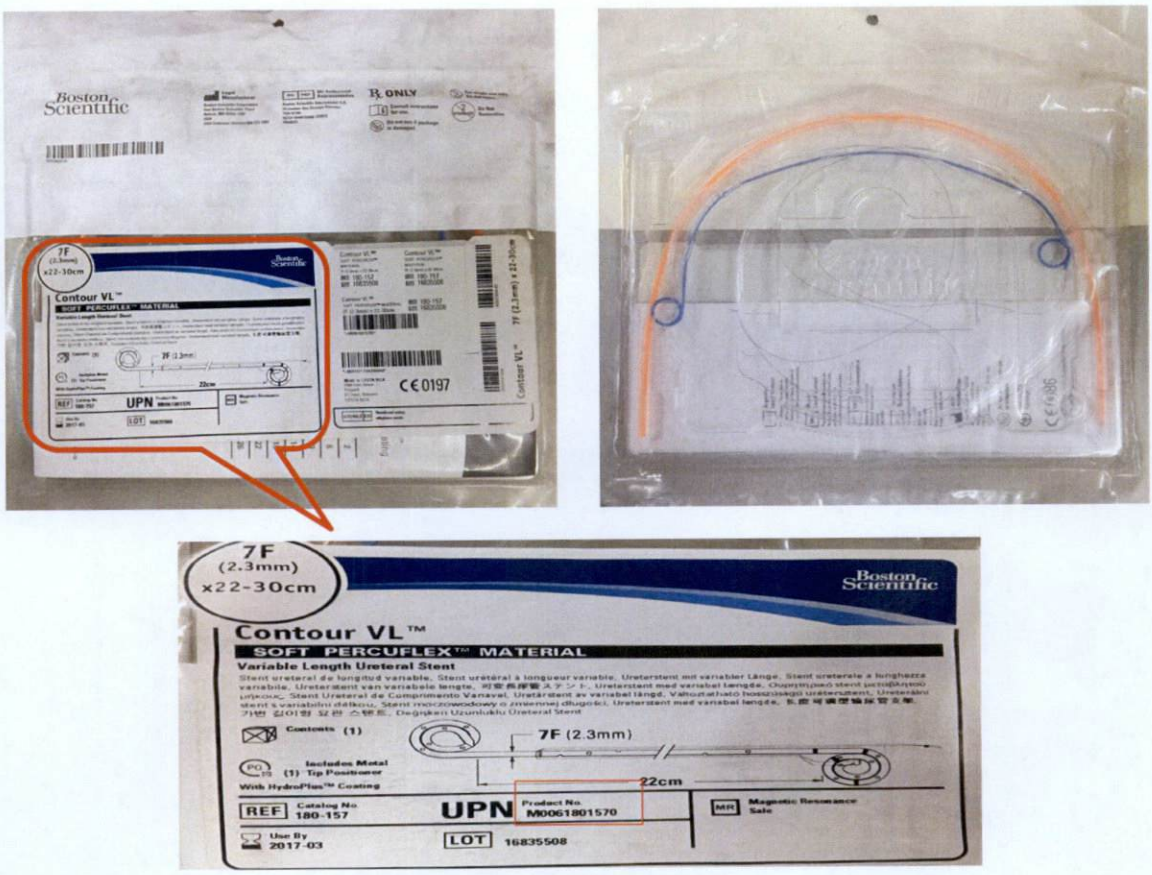

Figure 2. Unregistered Contour VL™ – Soft Percuflex™ Material – Variable Length Ureteral Stent (Product No. M0061801570)

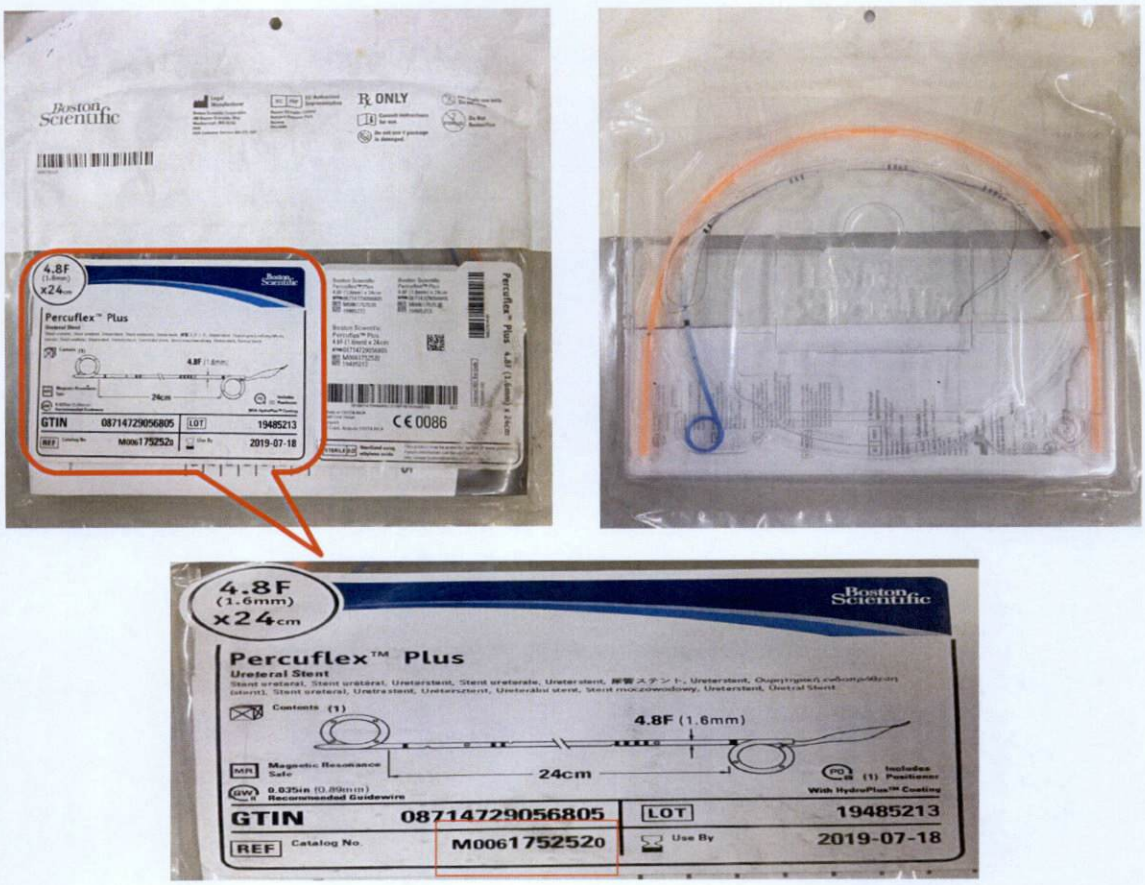

Figure 2. Unregistered Percuflex™ Plus - Ureteral Stent (Product No. M0061752520)

The FDA verified through post-marketing surveillance that the medical devices with the above-mentioned product number are not registered and no corresponding product registration certificate have been issued. Pursuant to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since these unregistered medical device products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety.

Furthermore, the FDA has verified that the above-stated unregistered medical device products are not imported by Boston Scientific Philippines, Inc.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products until the product registration certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label in the form of either DVR-xxxx or MDR-xxxx.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that these products are not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of these unregistered products.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@fda.gov.ph** indicating on the subject the concerned Advisory, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20191120144302