Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 AUG 2019

FDA ADVISORY
No. 2019-254

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Medical Device "INTROCAN SAFETY IV CANNULA WITH FIXATION WING (STERILE)" with the following Unregistered Article Numbers:**

SIZE	UNREGISTERED ARTICLE NUMBER
G16	4254570-01
G18	4254562-01, 4253604-01
G20	4254546-01
G22	4254511-01, 4253540-01
G24	4254503-01

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the medical device with the above-mentioned unregistered article numbers:

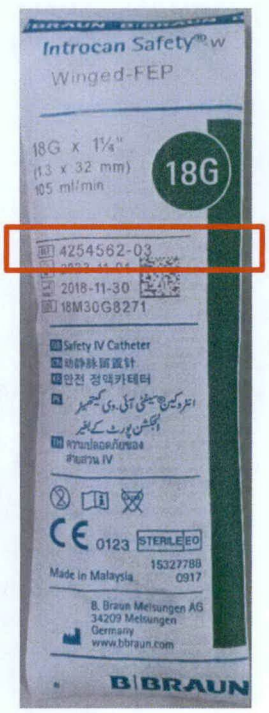

Figure 1. Front Label of a Sample of Registered Introcan Safety IV Cannula with Fixation Wing (Sterile)

Figure 2. Front Label of a Sample of Unregistered Introcan Safety IV Cannula with Fixation Wing (Sterile)

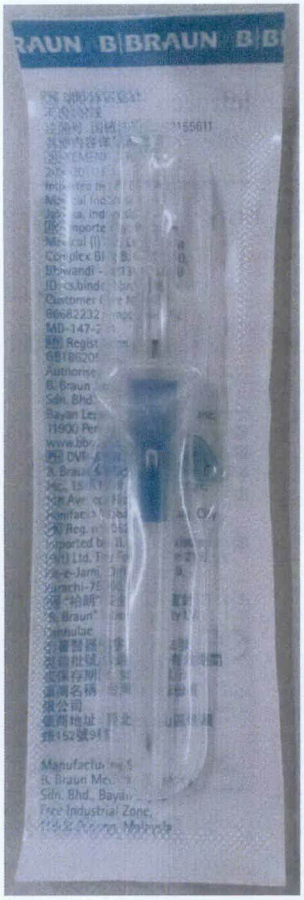

Figure 3. Photo of a Sample of Registered Introcan Safety IV Cannula with Fixation Wing (Sterile)

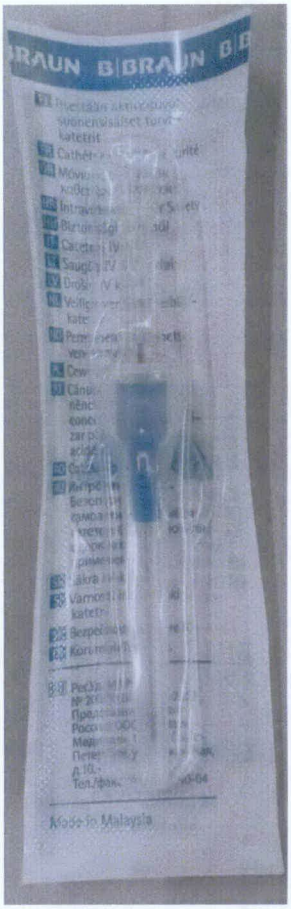

Figure 4. Photo of a Sample of Unregistered Introcan Safety IV Cannula with Fixation Wing (Sterile)

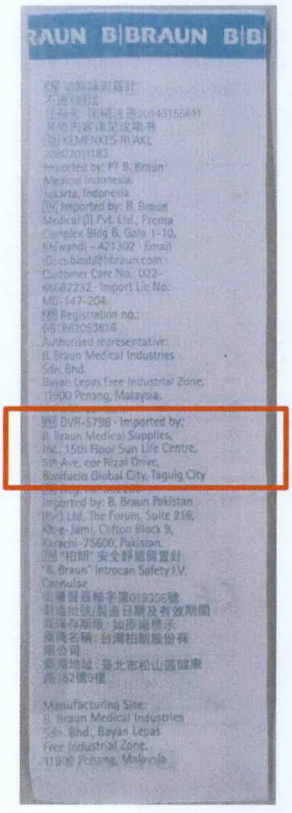

Figure 5. Inside Label of a Sample of Registered Introcan Safety IV Cannula with Fixation Wing (Sterile) with CPR Number and Importer's Name and Address

Figure 6. Inside Label of a Sample of Unregistered Introcan Safety IV Cannula with Fixation Wing (Sterile)

The FDA verified through post-marketing surveillance that the medical device with the above-mentioned article numbers is not registered and the Certificate of Product Registration (CPR) has not yet 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 this unregistered medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

Furthermore, FDA has verified that the above-stated unregistered medical device product is not imported by B. Braun Medical Supplies, Inc.

In light of the foregoing, the public is advised not to purchase the violative product in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device until CPR is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that this product is not sold or made available in the market or their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unregistered product.

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) 857-1900 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, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

DTN 20190508144427