Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA ADVISORY**
No. 2022-1626

20 SEP 2022

**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. **"INTROCAN® – W I.V. CANNULA 24G X 3/4" (0.7 X 19 MM)"**
2. **"INTROCAN® – W I.V. CANNULA 18G X 1 3/4" (1.3 X 45 MM)"**

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

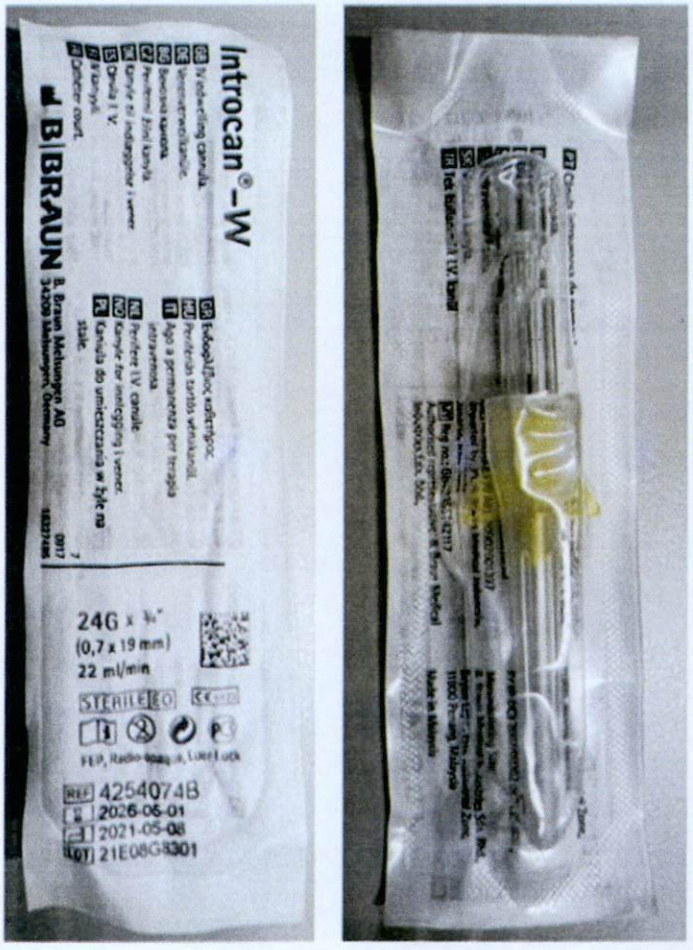


Figure 1. Unregistered Introcan® – W I.V. Cannula 24G x 3/4" (0.7 x 19 mm)

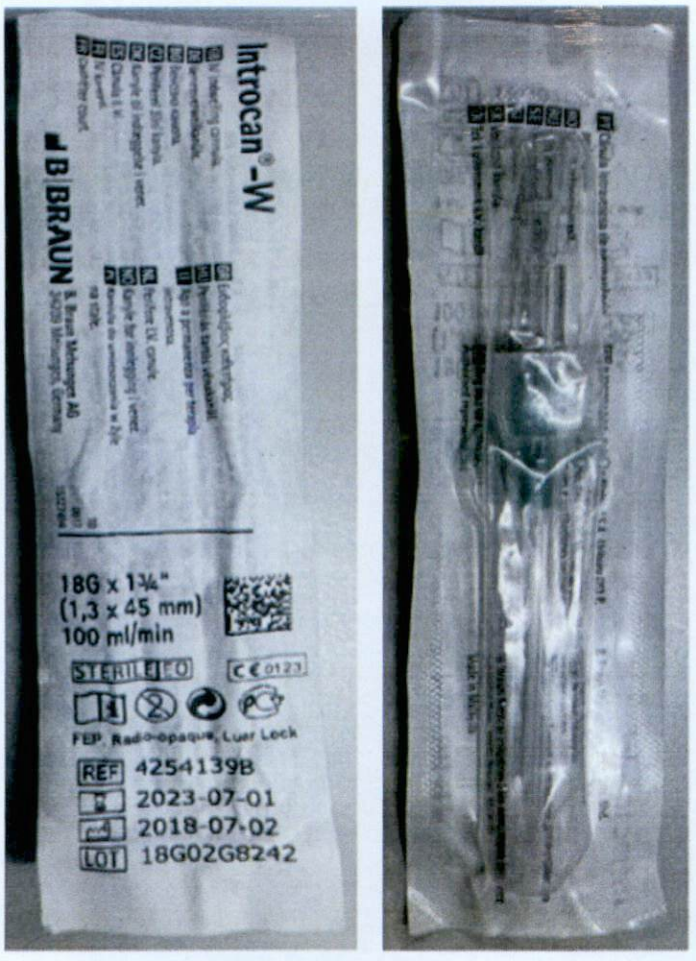


Figure 2. Unregistered Introcan® – W I.V. Cannula 18G x 1 3/4" (1.3 x 45 mm)

The FDA verified through post-marketing surveillance that the abovementioned medical device products are not registered and no corresponding Product Registration Certificates 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.

Furthermore, the FDA, in coordination with B. Braun Medical Supplies, Inc. verified that the above-stated medical device products are not included in their list of registered medical device products and that they were not responsible in the importation and distribution of the subject products in the country.

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

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 CMDR-xxx, DVR-xxx or MDR-xxx.

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 product.

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, contact the online reporting facility eReport through e-mail at **ereport@fda.gov.ph.**

Dissemination of this advisory to all concerned is hereby requested.

**DR. SAMUEL A. ZACATE**
Director General

DTN 20220612172109 & 20220612172003