



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2020-158**

13 FEB 2020

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Counterfeit Medical Device “Cos-Med Volumetric Solution Infusion Set”

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the counterfeit Cos-Med Volumetric Solution Infusion Set. Please see particulars/details of the original vs. the counterfeit product as provided below:

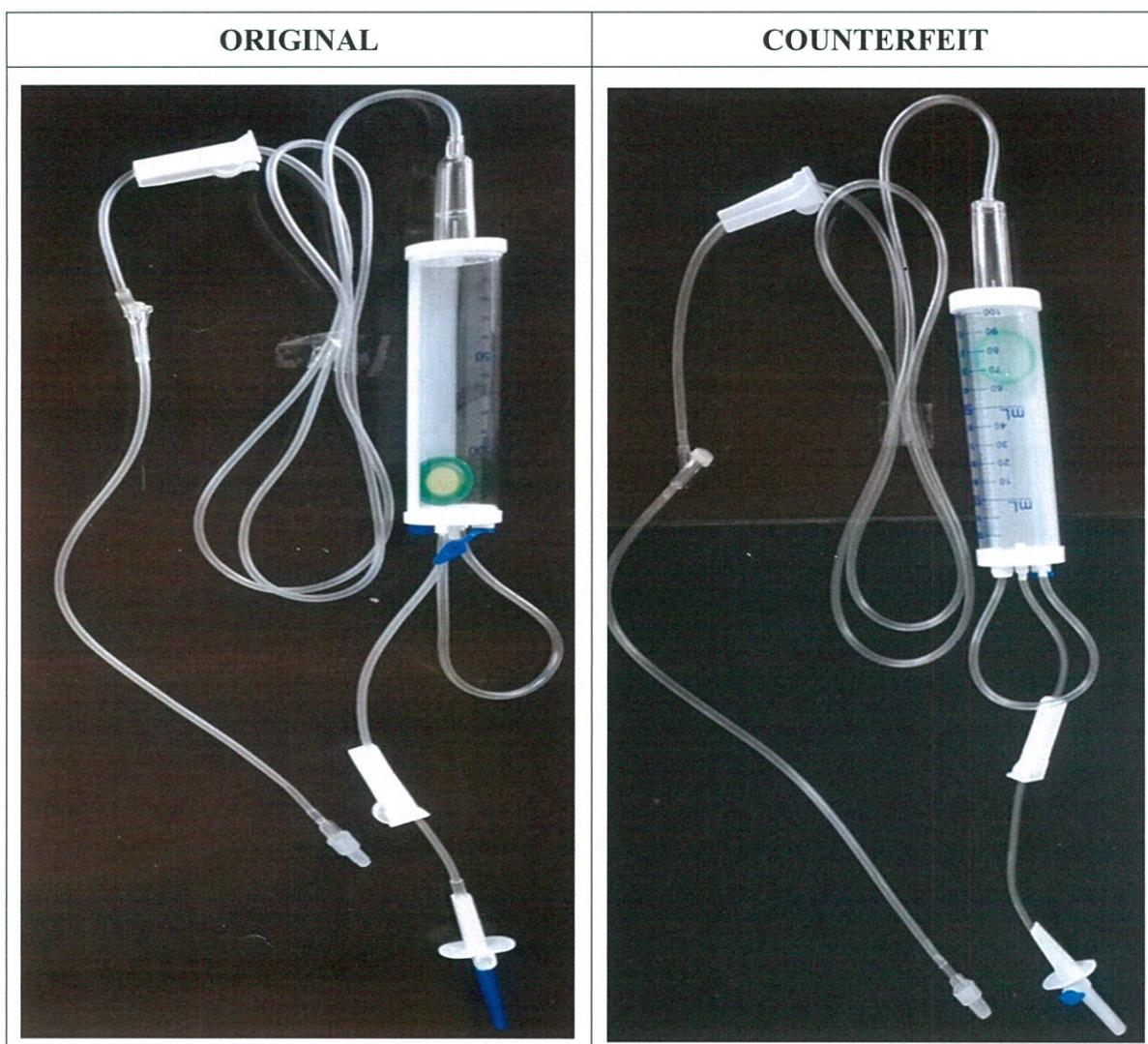


Figure 1. Photo of the Original and the Counterfeit Cos-Med Volumetric Solution Infusion Set



Product Details	ORIGINAL	COUNTERFEIT
Spike	airvented without airvent cap, with dark blue spike cap, fully wrapped-around spike	airvented with blue airvent cap, not fully wrap-around spike, clear spike cap
Roller and Clamp Case	both ABS Natural	both PVC white
Tubing	non-dehp PVC, slightly cloudy (opaque)	clear, smaller inner diameter (id) and od than original
Airvent Cap of Upper Cover of Barrel	dark blue, slightly triangular cap	dark blue, slightly triangular cap different model
Filter of Injection Port Cap of Upper Cover of Barrel	dark blue around the injection port	none
Barrel	firm, long and thin	slightly soft, short and bigger diameter
Diaphragm / Volumetric Coin	green rim with brown center	light green rim with see-thru center
Chamber	bottom is slightly rounded	bottom is squared
Y-site	with finger grip guard, brownish	no finger grip guard, beige in color, shorter
Connector	longer luer connector	shorter luer connector

Table 1. Comparison of the Original and the Counterfeit Cos-Med Volumetric Solution Infusion Set



Figure 2. Front Photo of the Original and the Counterfeit Polybag of Cos-Med Volumetric Solution Infusion Set

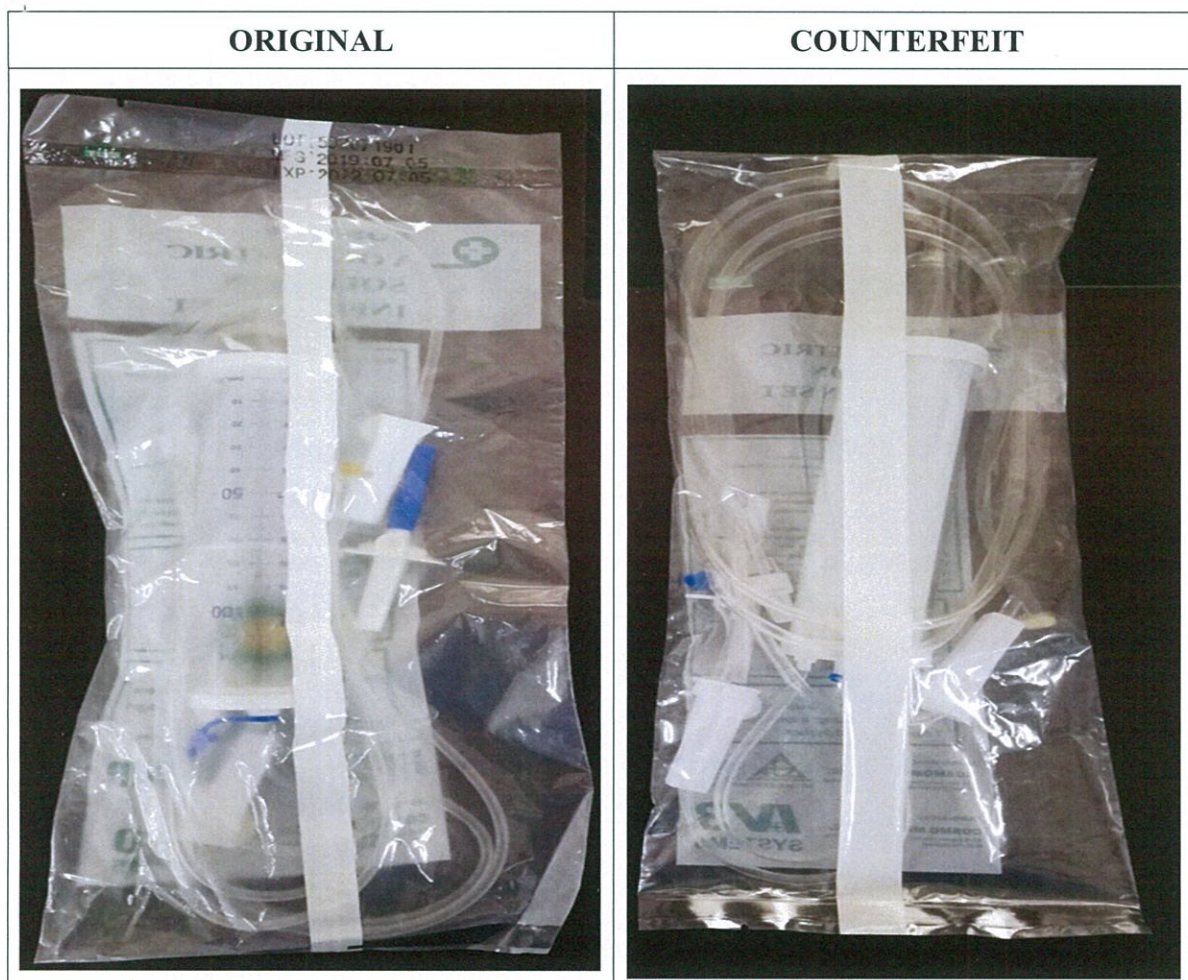


Figure 3. Back Photo of the Original and Counterfeit Polybag of Cos-Med Volumetric Solution Infusion

Polybag Details	ORIGINAL	COUNTERFEIT
Size	165mm x 405mm	smaller than original product
Product Code	incorporated in the Lot No.	no product code
Lot No. Manufacturing Date Expiration Date	<ul style="list-style-type: none"> Although there are pre-printed provisions for Lot No., Mfg. and Exp. Date in the left, topmost front of the polybag, this information were stamped at the topmost back of the polybag due to bigger printer font size These are not pre-printed Separated by spaces Printed in Black 	<ul style="list-style-type: none"> Lot No., Mfg. and Exp. Date are pre-printed in the bottom front of the polybag Lot No. is not same as the company format for Lot numbering Separated by dashes Pre-printed in green
Others	<ul style="list-style-type: none"> Uses ISO 13485 and GMP without the issuing company logo due to change of the certifying body The center of white ribbon packing strip at back of polybag is free of laminate 	<ul style="list-style-type: none"> Uses ISO 13485 and GMP with the company logo of the previous certifying body The entire of white ribbon packing strip at back of polybag is laminated

Table 2. Comparison of the Original and Counterfeit Polybag of Cos-Med Volumetric Solution Infusion Set



Figure 4. Photos of the Original and Counterfeit Carton Box of Cos-Med Volumetric Solution Infusion

ORIGINAL	COUNTERFEIT
Corrugated box is sturdy	Corrugated box is soft and easily crumble
Light brown color of carton box with white triangular marker on the left, topmost part on the front and back panels	Dark brown color of carton box with grayish triangular marker on the left, topmost part on the front and back panels
Font colors are light green	Font colors are dark green
Font style are more pronounced	Font style is narrow

Table 3. Comparison of the Original and Counterfeit Carton Box of Cos-Med Volumetric Solution Infusion Set

The Market Authorization Holder (MAH), Cosmo Medical, Inc., reported to the FDA that the aforementioned medical device is counterfeit.

Counterfeit product has not go through the required safety assessment and the FDA verification process. This product pose potential health hazards to the consuming public since its safety and purity cannot be guaranteed.

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

All concerned establishments are warned not to distribute, the said counterfeit medical device.


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 violative 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 counterfeit 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) 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, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

DTN: 20190913151641