Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 DEC 2017

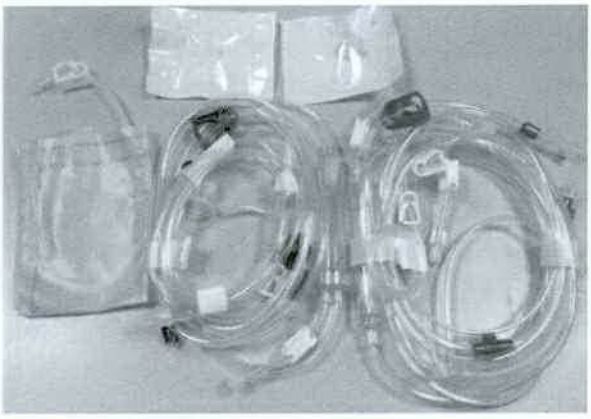
FDA ADVISORY
No. 2017-329

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

SUBJECT: **Voluntary Recall of AV-Set B DT INF-E Blood Tubing System with DVR No. 8574 (Article No. AP16641)**

All are hereby advised by the Food and Drug Administration (FDA) about the voluntary recall of the following batches of AV-Set B DT INF-E Blood Tubing System (see Figures 1 and 2) with DVR No. 8574. The said products were imported and distributed by Fresenius Medical Care Philippines, Inc. with office address at Chino Roces Avenue, Makati City.

Product Name: **AV-Set B DT INF-E Blood Tubing System**					
Certificate of Registration Number: **DVR-8574**					
Article No. : **AP16641**					
	Batch Number		Batch Number		Batch Number
1	**YBC132**	18	**YGC142**	35	**YBC144**
2	**YCC092**	19	**YGC152**	36	**YBC153**
3	**YDC262**	20	**YBC181**	37	**YBC181**
4	**YDC271**	21	**YCC043A**	38	**YCC032**
5	**YDC282**	22	**YCC122**	39	**YCC043A**
6	**YDC301**	23	**YCC301**	40	**YCC081**
7	**YEC013**	24	**YDC012**	41	**YCC092**
8	**YEC031**	25	**YDC262**	42	**YCC122**
9	**YEC053**	26	**YDC271**	43	**YDC011**
10	**YEC294**	27	**YDC282**	44	**YDC262**
11	**YFC012**	28	**YDC301**	45	**YDC271**
12	**YFC023**	29	**YEC013**	46	**YDC282**
13	**YFC091**	30	**YEC031**	47	**YDC301**
14	**YFC103**	31	**YEC053**	48	**YEC013**
15	**YFC113**	32	**YEC063**	49	**YEC031**
16	**YGC102**	33	**YEC294**	50	**YEC053**
17	**YGC131**	34	**YBC132**	*nothing follows*	



Figures 1 and 2: Photos of AV-Set B DT INF-E Blood Tubing System

The above-stated medical device products are being voluntary recalled by Fresenius Medical Care Philippines, Inc. because small clamps located at pre-pump position of T connector and post-pump positions of arterial and venous chamber may not close properly and could in some cases lead to blood leakage during treatment.

Distributors, retailers, hospitals and all healthcare professionals/users are advised to discontinue further distribution, sale and use of the said affected medical device product.

Any suspected adverse reaction experienced from the use of the device but not limited to the lot stated above, should be reported immediately to FDA at telephone number (02) 857-1900 local 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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