

Urgent Field Safety Notice

Recall of 4008 bloodlines (AV-Set B-R F00001124 and AV-Set SRB-R F00000257) due to blood leakages

Date: August 28th, 2019

Dear Madam/ Sir *(to be adapted locally)*,

During the continuous market surveillance of our 4008 bloodlines, we have become aware of an increased number of blood leakages caused by a rupture of the tube with batches produced in November 2018 (please see below table).

Article	Affected batches					
F00001124 AV-Set B-R	ZRSL051	ZRSL071	ZRSL091	ZRSL131	ZRSL141	ZRSL161
	ZRSL171	ZRSL191	ZRSL201	ZRSL232	ZRSL271	
F00000257 AV-Set SRB-R	ZRSL061	ZRSL062	ZRSL081	ZRSL121	ZRSL211	ZRSL212
	ZRSL221	ZRSL231	ZRSL241	ZRSL261	ZRSL281	ZRSL282
	ZRSL291	ZRSL292				

In the reported cases the leakage occurred during the treatment and resulted in blood loss which cannot be detected by the dialysis machine. Therefore, there might be a potential serious risk for the patient if affected bloodlines are used.

To avoid the risk of blood leakages or air entry we ask you to immediately stop using the affected product batches.

Please provide this Recall Notice to all users of the above-mentioned bloodlines in your organization and other persons concerned.

We sincerely apologize for any inconvenience this may cause and we will provide you with a replacement as soon as possible. Fresenius Medical Care is committed to ensuring our products and services consistently meet the highest standards of quality and safety for patients and healthcare providers.

You will be contacted by your local Fresenius Medical Care representative to organize the replacement of the affected bloodlines.

In case of any further questions do not hesitate to contact:

Name (*Please adapt locally*)

Telephone (*Please adapt locally*)

E-mail XXX@fmc-ag.com (*Please adapt locally*)

Sincerely yours,

Name and Signature (*please adapt locally*)