Urgent Field Safety Notice

Artis Cartridge, Cartridge Single Needle and Cartridge Set, Standard Prime Line
FA-2020-068
Safety Alert

January 2021

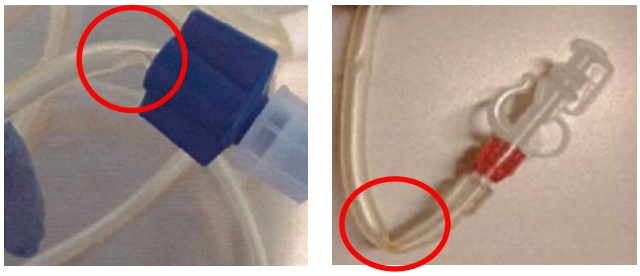
Dear Healthcare Provider:

Problem Description

Baxter Healthcare Corporation has received customer reports of kinked access lines observed during treatment using cartridge sets for hemodialysis treatments.

Kinked access lines can be detected prior to use. The various products' Instructions for Use (IFU) advise customers to make sure the tubing system and patient vascular access are not kinked, and to avoid kinking of the tubing during set-up or during the treatment.

Baxter is asking that customers check the cartridge sets for kinked tubing prior to use and not use sets with kinked tubing for hemodialysis treatments. The pictures below show examples of kinked tubing.



Affected Product

Product Code	Product Description	Lot Number
114614	Cartridge Single Needle	All lots within expiry
955075	Artiset HD DNL HC	All lots within expiry
955077	Artiset Prepost	All lots within expiry
114510	Cartridge with Hemoscan	All lots within expiry
114533	Artiset HD SN HC	All lots within expiry
114598	Cartridge Extended Patient Lines	All lots within expiry
114599	Cartridge Ext/ Patient Lines + Infusion	All lots within expiry
114611	Cartridge Standard	All lots within expiry
114612	Cartridge Low Weight	All lots within expiry
114613	Cartridge Low Weight Low Volume	All lots within expiry
955526	Physioset HD DNL HC	All lots within expiry
955527	Physioset Prepost	All lots within expiry

Hazard Involved

A kinked access line has the potential to cause delay in therapy, blood circuit clotting as a result of reduced blood flow, or hemolysis. There has been one report of serious injury (hemolysis) potentially associated with this issue.

Actions to be Taken by Customers

1. Customers can continue to safely use the affected cartridge sets listed above by inspecting sets prior to use as advised in the relevant IFU. If a kink is identified during inspection, the cartridge set must not be used. If a kink is identified during treatment, therapy must be interrupted, and the set must be replaced to restart therapy.

2. If you identify sets with kinked tubing, please contact Baxter Healthcare Center for Service to arrange for return and credit.

3. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by faxing it or scanning and e-mailing it or sending it by post. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to customers.

Further information and support

For general questions regarding this communication, contact Baxter.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Baxter Healthcare Corporation