Urgent Field Safety Notice

ARTISET HD DNL HC; ARTISET PREPOST
FA-2019-055
RECALL

October, 2019

Dear Healthcare Provider:

Problem Description

Baxter Healthcare Corporation is issuing a voluntary product recall for the ArtiSet Blood Tubing Sets listed below due to the potential for an occlusion of the blood circuit pathway just after the pump segment.

Affected Product

Product Code	Product Description	Lot Number
955075	ARTISET HD DNL HC	1000218861
		1000218859
		1000218860
		1000220524
		1000218864
955077	ARTISET PREPOST	1000218875

Hazard Involved

Occlusion of the blood tubing set may result in delay in therapy or minor blood loss; however, serious adverse health consequences are not expected. There have been no reports of serious injury associated with this issue.

Actions to be taken by Customers

1. Locate and remove the affected product lots from your facility. The product code and lot number can be found on the individual product and/or shipping carton. Contact Baxter Healthcare Center for Service to arrange for return and credit.

2. Since only certain lots are impacted by this Recall, you can continue to order other unaffected lots of the ArtiSet Blood Tubing Sets.

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, even if you do not have any inventory. 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 conduct a consumer-level recall of the affected product that you distributed to customers.

We apologize for any inconvenience this may cause you, your team, and our patients.

Sincerely,

Baxter Healthcare Corporation