URGENT PRODUCT RECALL

Dec 19, 2016

Dear Dialysis Provider:

Baxter Healthcare Corporation is voluntarily recalling one lot of Ultrafilter (product U9000, lot 6-1804-H-01). The manufacturing team noticed the potential of defective filters based on an improper molded Hansen lock. The reported issue is specific to this one lot and others lots not impacted.

Affected Product

Product Code	Description	Lot Number
114604	Ultrafilter U9000	6-1804-H-01

Problem Description

Baxter identified increase of defective filters during Leak testing and this is a single isolated manufacturing issue related to a molded Hansen lock for the above mentioned lot .The complaint database was searched from 2014-Jan to 2016-ytd and there were no complaints with leakage at the Hansen lock identified.

Hazard Involved

The disinfection cycle will stress the material and there is the potential that the improper molded parts will become defective. The parts with the uncorrected molding flow line could lead to fluid leakage.

Action to be taken if you are an end-user and product was purchased directly from Baxter

Baxter is requesting that you take the following actions:

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product package or shipping carton.
2. Contact Baxter Healthcare Center for Service to arrange for return and credit.
3. If you received your product directly from Baxter, please complete the enclosed customer reply form, and return it to Baxter by either fax or scanned e-mail.

Action to be taken if you are an end-user and purchased product from a distributor or reseller

1. If you ordered product from a dealer, wholesaler, or distributor/reseller, please follow your supplier's reply and recall process.
2. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product package or shipping carton.
3. Please do not return the Baxter customer reply form to Baxter. Reply forms should be returned to your supplier.

Action to be taken if you are a Distributor

If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please conduct a recall with your end-user customers in accordance with your customary procedures.

We apologize for any inconvenience this communication may cause you. The Taiwan FDA has been notified of this action.

We look forward to continuing to serve your dialysis needs and we thank you for your cooperation.

Sincerely,

Diorio, Simone
Vice President Quality-Renal
Baxter Healthcare