# BAXTER HEALTHCARE PRODUCT RECALL

**Problem Description**

Baxter Healthcare Corporation is issuing a voluntary product recall for all unexpired lots of the 50mm 0.2 Micron Filter (Product Code: H93835) due to the potential for the filter membrane layer to be missing and for particulate matter to be present. The affected lots were distributed between 8/22/2013 and 6/20/2016.

**Affected Product**

| Product Code | Product Description | Lot Numbers | Expiration Dates |
|---|---|---|---|
| H93835 | 50mm 0.2 Micron Filter | All unexpired lots | 6/27/2016-6/27/2019 |

**Hazard Involved**

The 50mm 0.2 Micron Filter is a bacteria and particulate filter for aqueous solutions used during the compounding of solutions. In the absence of the filter, any bacteria present in unsterile solution may pass through to the compounded preparation. If not further filtered or sterilized before administered to a patient, this could result in blood stream contamination. Similarly, any particulate matter present in the unsterile solution would pass through to the compounded product. If not further filtered before patient administration, this could lead to adverse health consequences. To date, there have been no reports of adverse events associated with this issue.

**Actions to be taken if product was purchased directly from Baxter**

1. Locate and remove all affected product lots from your facility. The product code, lot, and expiration date can be found on the individual product or shipping carton.

2. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.

3. Complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to **fca@baxter.com**. Returning the Baxter customer reply form promptly will prevent you from receiving repeat notices.

4. If you distribute this product to other facilities or departments within your institution (e.g., Pharmacy, ER, ICU, NICU, PICU), please forward a copy of this communication to them.

5. 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 lots that you distributed to customers.

**Action to be taken if product was purchased from a distributor**

1. Locate and remove all affected product lots from your facility. The product code, lot, and expiration date can be found on the individual product or shipping carton.
2. Contact Baxter Healthcare Center for Service to arrange for return and credit. The Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.
3. 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.

**Further information and support**

For general questions regarding this communication, contact Baxter Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions or quality problem experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00am and 5:00pm Central Time, Monday through Friday.
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  **Online:** By completing and submitting the report online at:www.fda.gov/medwatch/report
  **Regular mail:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form:
  MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
  **Fax:** Submit to 800-332-0178