

## FOR IMMEDIATE RELEASE

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## BAXTER INITIATES VOLUNTARY RECALL OF ALL UNEXPIRED LOTS OF 50MM 0.2 MICRON FILTERS

DEERFIELD, III., September 27, 2016 – Baxter International Inc. announced today it is voluntarily recalling all unexpired lots of 50mm 0.2 micron filters (product code H93835) due to the potential for a missing filter support membrane and for potential presence of particulate matter. These issues are associated with a component manufactured by an external supplier, and were identified prior to patient involvement as a result of complaints from customers at compounding facilities. There have been no adverse events reported to Baxter to date associated with these issues.

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 support membrane, bacteria and/or particulate matter present in an unsterile solution could pass through to the compounded prepared solution. If not further filtered before patient administration, this could lead to adverse health consequences.

The recall affects the following lots:

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



The lots being recalled were distributed to customers and distributors globally between August 22, 2013 and June 20, 2016. Baxter is directing customers not to use the product from the recalled lots. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7 a.m. and 6 p.m., Central Time. Although the product has been discontinued for reasons unrelated to this recall, Baxter will work with customers to direct them toward suitable alternative products, if necessary.

Customers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8 a.m. and 5 p.m. Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.



Baxter is voluntarily conducting this recall with the knowledge of the U.S. Food and Drug Administration.

## **About Baxter**

Baxter International Inc. provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; biosurgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

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