

U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

Baxter Healthcare Corporation, INTRAVIA Empty Containers with PVC Ports – Particles Found in Patient Solution

Recall Class: Class I

Date Recall Initiated: September 16, 2014

Devices:

1. INTRAVIA Empty Container with PVC Ports, (Sterile, fluid path), 150 mL, Product Code 2B8011, Lot No. UR13D15112
 - Manufacturing Date: April 18, 2013
 - Distribution Dates: April 26, 2013 to June 20, 2013
2. INTRAVIA Empty Container with PVC Ports (Sterile, nonpyrogenic fluid path), 500 mL, Product Code 2B8013, Lot No. UR13K14095
 - Manufacturing Date: November 18, 2013
 - Distribution Dates: November 27, 2013 to March 10, 2014

Devices with lot numbers that are not part of this recall can be used.

Use: An INTRAVIA Empty Container is used to prepare liquid medicines given to patients through a tube attached to a needle that is inserted into a vein. The primary users of these devices are hospitals and clinics.

Recalling Firm:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Reason for Recall:

Baxter Healthcare found visible particles in INTRAVIA Empty Containers. These particles might be found in the solution in the tube that leads from a container to a patient's vein.

These particles may irritate the patient's veins, cause pain, worsen a previous infection, cause allergic reactions, block blood vessels, and cause death.

No injuries have been reported.

Public Contact: For questions about this recall, contact Center for One Baxter at 1-800-422-9837 or 847-948-4770, Monday through Friday, 8:00 am – 5:00 pm, Central Time.

FDA District: San Juan District Office

More Information about this Recall:

Baxter Healthcare sent customers an Urgent Product Recall letter on September 10, 2014. The letter included the following advice for customers:

- Locate and remove all recalled devices from your facility.
- Contact Baxter Healthcare Center for Service to arrange for return of the recalled devices.
 - Call 1-888-229-0001, Monday through Friday, 7:00 am – 6:00 pm, Central Time.
 - Provide Baxter's 8-digit ship-to-account number when calling.
- Complete the customer reply form enclosed with the Urgent Product Recall letter and return it to Baxter either by fax or scanned email.
- Notify customers who may have received the recalled devices through re-distribution.

Other Information:

- [Firm Press Release \(/Safety/Recalls/ucm420402.htm\)](/Safety/Recalls/ucm420402.htm)
- [Product Labels \(Photo\) \(/Safety/Recalls/ucm420403.htm\)](/Safety/Recalls/ucm420403.htm)

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program \(https://www.accessdata.fda.gov/scripts/medwatch/\)](https://www.accessdata.fda.gov/scripts/medwatch/) either online, by regular mail or by FAX.