URGENT MEDICAL DEVICE RECALL

June 30, 2026

Dear Medical Director:

Baxter Healthcare Corporation is issuing an Urgent Medical Device Recall for three lots of **Duo-Vent** solution sets listed below due to customer reports of air bubbles in the drip chamber and tubing when a pressure cuff is in use or when the tubing is flushed at the fully open position. The affected lot numbers were distributed from 5/28/2026 to 6/24/2026 in the United States.

Affected Product

Product Code	Product Description	Lot Number	Expiration Date	UDI-DI Number
1C8507	**Duo-Vent** Solution Set and Male Luer Lock Adapter. 10 drops/ mL.109" (2.8 m). Sterile package	DR26C27062	30-Mar-2028	00085412014319
		DR26D14031	15-Apr-2028	
		DR26E13055	14-May-2028	

Hazard Involved

This issue may result in air entering the administration set when pressure is applied to the bag (e.g., via a pressure cuff) or when the tubing is flushed while fully open. If an infusion pump with an air-in-line detector is not in use—as may be the case during pressure infusions—there is a potential for air to be delivered through the IV line to the patient.

In most cases, small amounts of air are absorbed in the lungs without causing harm. However, in patients with certain cardiac or vascular conditions (such as a patent foramen ovale or other right-to-left shunts), the presence of air in the circulation may lead to serious adverse events, including stroke, myocardial ischemia, or death.

Actions to be Taken by Customers

1. Immediately locate, isolate, and cease all use of the affected lot numbers of the product. The product code and lot number can be found on the individual product package and shipping carton.
2. Contact Baxter Healthcare Center for Service to arrange for return and replacement product 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. If you received this communication directly from Baxter, please acknowledge receipt of this notification by following the instructions on the enclosed reply instruction sheet, even if you have no remaining inventory. Acknowledging receipt will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from Accenture LLP on behalf of Baxter to confirm your receipt of this notification.
4. If you purchased this product from a distributor or wholesaler, please contact them to arrange for return of the affected product. Please note that responding to Baxter is not applicable. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.

5. Please forward a copy of this communication to the director of nursing, director of pharmacy, director of purchasing, facility risk manager, and any other departments within your institution who use the affected product.
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 user-level recall of the affected product that you distributed to customers and check the associated box on the customer portal**.**

Further Information and Support

For general questions regarding this communication, please contact Baxter Healthcare Center for Service at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.

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

- Contacting Baxter Product Surveillance at the Baxter product feedback portal at https://productfeedback.baxter.com, or emailing Baxter at corporate_product_complaints_round_lake@baxter.com
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
    - **Online:** By completing and submitting the report at www.accessdata.fda.gov/scripts/medwatch
    - **Regular mail or Fax:** 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 or submit by fax to 800-332-0178

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Zulfiqar Ali

Zulfiqar Ali
Director, Design Quality
Baxter Healthcare Corporation

Enclosure: Baxter Reply Instruction Sheet