

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

On August 20, 2024, and October 18, 2024, Baxter issued Urgent Medical Device Correction letters for the automated compounding device Inlets listed below used with **ExactaMix** and **ExactaMix Pro** compounders. The letters addressed particulate matter observed before use within the inlet primary packaging and inlet components, including within the sterile fluid path. The affected product was distributed to customers from 9/29/2021 to 1/6/2025 in the United States.

Baxter has replenished our supply of acceptable replacement inlets and is now advising customers to locate and remove the affected lot numbers of the product listed below from their facilities. Customers should cease use of the affected lot numbers of the product.

Particulate matter in the sterile fluid pathway may end up in the final admixture if the priming cycle during compounder setup does not remove it into a discard bag. If the particulate matter is unnoticed and the infusion is delivered, there is potential for serious or critical adverse health consequences if an in-line filter is not used during the infusion. If the particulate matter is noticed and the product discarded, a delay in parenteral nutrition therapy of up to 12 hours may result. To date, Baxter has not received any reports of patient injury related to this issue.

Product Code	Product Description	Lot Numbers	Expiration Date	UDI Number
H938173	Automated Compounding Device Inlet. Non-Vented, High-Volume Inlet	803806 and lower	10/3/2025-7/8/2027	00085412475783
H938174	Automated Compounding Device Inlet. Vented High-Volume Inlet	803799 and lower	10/14/2025 - 6/24/2027	00085412475790
H938175	Automated Compounding Device Inlet. Vented, Micro-Volume Inlet	803808 and lower	10/4/2025-7/9/2027	00085412475806

H938176	Automated Compounding Device Inlet. Syringe Inlet	803807 and lower	10/6/2025- 7/10/2027	00085412475813
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