URGENT MEDICAL DEVICE CORRECTION

Follow-up Communication to August 20, 2024, Urgent Medical Device Correction

October 18, 2024

Dear Director of Pharmacy, Pharmacy Staff, and Medication Safety Officer:

On August 20, 2024, Baxter issued an Urgent Medical Device Correction letter for Automated Compounding Device Inlets. This letter has been revised to include updated lot numbers and expiration dates in the Affected Product section. The updated information in this section is in bold. Please note that Baxter has established an end point for lots affected by this field action. Once Baxter has sufficient supply of acceptable replacement product available, a follow-up notification will be sent to customers to provide additional information. Until this occurs, please continue to follow the steps outlined in the 'Actions to be Taken by Customers' section of this letter for the affected lot numbers.

Problem Description

Baxter Healthcare Corporation has received increased customer reports of particulate matter in the Automated Compounding Device Inlets (disposable inlet) listed below used with the EXACTAMIX and EXACTAMIX PRO compounders. Particulate matter has been observed within the inlet primary packaging and inlet components, including within the sterile fluid path tubing, before use. This issue only affects the disposable inlets and does not affect the EXACTAMIX or EXACTAMIX PRO compounder devices. The affected product was distributed to customers beginning on 9/29/2021 in the United States.

Baxter is working expeditiously to replace the affected product codes listed below, as only Baxter's disposable inlets are qualified for use with the EXACTAMIX and EXACTAMIX PRO compounders. During this period, customers who do not observe particulate matter may continue to use the inlets as outlined in the 'Actions to be Taken by Customers' section of this letter. Customers should not use the disposable inlet if particulate matter is observed. The EXACTAMIX and EXACTAMIX PRO compounding devices can continue to be used with inlets where no particulate matter is observed.

Once the issue is resolved and customers can order replacement EXACTAMIX inlets, Baxter will send a follow-up notification.

Affected Product

Product Code	Product Description	**Lot Numbers**	**Expiration Date**	UDI Number
H938173	Automated Compounding Device Inlet. Non-Vented, High-Volume Inlet	**803806 and lower**	**11/23/2024 – 7/8/2027**	00085412475783
H938174	Automated Compounding Device Inlet. Vented, High-Volume Inlet	**803799 and lower**	**10/21/2024 – 6/24/2027**	00085412475790
H938175	Automated Compounding Device Inlet. Vented, Micro-Volume Inlet	**803808 and lower**	**10/20/2024 – 7/9/2027**	00085412475806
H938176	Automated Compounding Device Inlet. Syringe Inlet	**803807 and lower**	**11/10/2024 – 7/10/2027**	00085412475813

Hazard Involved

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.

Actions to be Taken by Customers

1. Disseminate this information to anyone who may interact with the EXACTAMIX and EXACTAMIX PRO compounders and the products they produce (Pharmacy and Clinical Staff).
2. Pharmacy Staff: Inspect the inlets before use, including the inlet primary packaging, tubing, connectors, and spikes. Perform the inspection in accordance with the enclosed instructions.
    - If particulate matter is observed, do not use the inlet and contact Baxter Corporate Product Surveillance to report the complaint and to arrange for the safe return of the product for further investigation, see contact information below. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when contacting Baxter. The product code and lot number can be found on the individual product pouch and carton.
    - If no particulate matter is observed, the inlet can be used for compounding. Please ensure the inlet is primed before use according to the instructions provided in the *Priming and Verifying* section of the EXACTAMIX and EXACTAMIX PRO compounder Operator's Manual.
3. Pharmacy and Clinical Staff: After compounding, visually inspect the finished solution in the patient bag for precipitates and particulates per the *Fulfilling the Order* section in the EXACTAMIX and EXACTAMIX PRO compounder Operator's Manual.
4. Use a minimum of 1.2 micron in-line filter during product administration. The American Society for Parenteral and Enteral Nutrition (ASPEN) recommends using a 1.2 microns in-line filter for administration of total nutrient admixtures (TNAs), dextrose-amino acid admixtures, and lipid injectable emulsion. If you are already using in-line filtration per ASPEN recommendation, no additional action is necessary.
5. Once Baxter has an acceptable replacement product available, a follow-up notification will be sent to customers to provide additional information. Until an acceptable replacement is available, please follow the steps outlined above, including inspection processes and the use of in-line filtration.
6. **If you received this communication directly from Baxter, please acknowledge receipt of this notification by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com even if you do not have any remaining inventory.** Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgment, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
7. If you purchased this product from a distributor or wholesaler, please note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.
8. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
9. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Urgent Medical Device Correction in accordance with your customary procedures 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 by 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,

Simone Diorio

Simone Diorio
Vice President, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Reply Form Instruction Sheet
Automated Compounding Device Inlets Inlet Visual Inspection Instructions

Automated Compounding Device Inlet Visual Inspection Instructions

1.0 Automated Compounding Device Inlet Product Description:

There are 4 different Automated Compounding Device Inlet (disposable inlet) product configurations. Each disposable inlet product includes tubing with different attached (capped) components on each end. The disposable inlets are sealed in a pouch (clear film on one side with white opaque Tyvek on the other side). The disposable inlets are sterile. See disposable inlet product photos below.

(Pictures above are shown without caps to show the different end components.)

Examples of Capped Inlet Products (without Packaging Pouch)

Automated Compounding Device Inlet Visual Inspection Instructions

Example of Capped Inlet (with Packaging Pouch and Unit Label)

2.0 Visual Inspection Instructions for Particulate Matter:

Perform visual inspection on each disposable inlet as follows:

1. Take the disposable inlet pouch in your hands.
2. Without opening the pouch, check each product, including the inlet primary packaging, tubing, connectors, and spikes, for at least 5 seconds at a distance of approximately 12 inches (30 centimeters) for visible particulate matter using the naked eye. The use of magnification or alternate light sources is not required for this inspection.
3. Identified visible particulate matter include, but are not limited to, embedded black spots, stains, fibers, and loose particles, noticeable to the naked eye, either inside or outside the disposable inlet itself, or inside the product packaging.
4. If visible particulate matter is found, do not use the disposable inlet. Follow the instructions provided in the Baxter customer letter. You may continue to use the **ExactaMix** or **ExactaMix Pro** compounding device with other disposable inlets that are inspected in accordance with the instructions above without identification of particulate matter.

