Baxter

URGENT MEDICAL DEVICE CORRECTION

August 20, 2024

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

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 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	UDI Number
H938173	Automated Compounding Device Inlet. Non-Vented, High-Volume Inlet	Refer to Attachment A	00085412475783
H938174	Automated Compounding Device Inlet. Vented, High-Volume Inlet		00085412475790
H938175	Automated Compounding Device Inlet. Vented, Micro-Volume Inlet		00085412475806
H938176	Automated Compounding Device Inlet. Syringe Inlet		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 Customer Reply Form Instruction Sheet
Attachment A: Affected Lot Numbers
Automated Compounding Device Inlets Inlet Visual Inspection Instructions

Baxter

Attachment A: Affected Lot Numbers of Automated Compounding Device Inlet Products

Product Code H938173 – Automated Compounding Device Inlet. Non-Vented, High-Volume Inlet

803240	803309	803347	803397	803450	803499	803552	803596	803637	803694	803734	803780
803242	803310	803348	803399	803451	803500	803555	803603	803644	803695	803735	803782
803261	803311	803349	803400	803455	803501	803566	803604	803645	803696	803738	803783
803268	803312	803351	803401	803456	803504	803567	803606	803646	803697	803739	
803270	803313	803352	803402	803472	803509	803568	803607	803647	803705	803740	
803271	803319	803353	803406	803473	803513	803573	803609	803654	803706	803741	
803274	803320	803358	803407	803479	803514	803574	803613	803655	803709	803742	
803289	803321	803359	803415	803480	803524	803577	803615	803659	803710	803752	
803295	803322	803360	803420	803485	803525	803579	803619	803665	803713	803762	
803298	803323	803366	803424	803486	803526	803580	803620	803666	803714	803763	
803302	803329	803367	803425	803488	803527	803581	803628	803667	803719	803764	
803303	803330	803368	803434	803492	803528	803582	803629	803671	803720	803767	
803304	803336	803369	803435	803493	803534	803583	803631	803672	803725	803768	
803305	803342	803372	803443	803494	803548	803584	803632	803679	803726	803769	
803306	803343	803373	803444	803495	803549	803594	803633	803680	803727	803770	
803307	803344	803396	803448	803498	803550	803595	803634	803681	803728	803779	

Product Code H938174 – Automated Compounding Device Inlet. Vented, High-Volume Inlet

803251	803279	803385	803412	803446	803489	803558	803588	803626	803690	803737
803256	803283	803386	803413	803447	803490	803559	803589	803660	803691	803758
803257	803291	803387	803414	803449	803538	803560	803590	803662	803700	803759
803258	803363	803388	803417	803461	803542	803572	803597	803663	803701	803795
803259	803370	803389	803419	803462	803543	803575	803602	803664	803702	803797
803260	803379	803405	803428	803464	803545	803576	803616	803687	803723	
803267	803382	803408	803433	803471	803556	803578	803617	803688	803724	
803278	803384	803409	803445	803478	803557	803586	803618	803689	803736	

Baxter

Attachment A: Affected Lot Numbers of Automated Compounding Device Inlet Products

Product Code H938175 – Automated Compounding Device Inlet. Vented, Micro-Volume Inlet

803238	803285	803335	803377	803421	803474	803518	803610	803653	803711	803754
803239	803287	803338	803378	803423	803481	803522	803611	803658	803712	803755
803246	803290	803339	803380	803426	803482	803532	803612	803673	803715	803765
803248	803292	803345	803381	803429	803484	803533	803621	803674	803716	803775
803252	803296	803346	803383	803430	803491	803535	803622	803675	803717	803776
803253	803301	803354	803390	803436	803496	803536	803623	803676	803718	803778
803254	803308	803355	803391	803437	803502	803539	803624	803678	803729	803781
803255	803314	803356	803392	803438	803503	803554	803625	803683	803730	803787
803263	803315	803357	803393	803439	803507	803561	803638	803684	803731	803790
803265	803316	803361	803394	803440	803508	803562	803639	803692	803743	803791
803276	803317	803365	803403	803442	803510	803564	803642	803693	803744	803792
803277	803324	803371	803404	803453	803511	803565	803643	803698	803745	803793
803280	803332	803374	803410	803454	803512	803591	803649	803699	803746	803801
803281	803333	803375	803411	803458	803515	803593	803650	803703	803747	803802
803282	803334	803376	803416	803465	803516	803608	803652	803704	803748	

Product Code H938176 – Automated Compounding Device Inlet. Syringe Inlet

803244	803275	803318	803341	803467	803477	803529	803553	803640	803707	803750
803247	803284	803325	803364	803468	803483	803530	803569	803657	803708	803751
803250	803286	803326	803431	803469	803506	803531	803571	803668	803721	803773
803262	803293	803328	803432	803470	803519	803537	803585	803669	803722	803794
803266	803297	803331	803459	803475	803520	803546	803599	803685	803732	
803272	803299	803340	803463	803476	803521	803547	803600	803686	803733	

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.

