URGENT MEDICAL DEVICE CORRECTION

Baxter EXACTAMIX Valve Set Port Leakage – Risk of Incorrect Final Admix

July 14, 2022

Dear Office of Regulatory Affairs, Director of Pharmacy and Pharmacy Staff, and Clinical and Nursing Staff:

Problem Description

Baxter is issuing an Urgent Medical Device Correction communication regarding the potential for leaking valves in the EXACTAMIX 2400 Valve Sets. Baxter has observed an increase in complaints for leaking of ports 1 and 2 when in the closed position, resulting in unintended ingredient transfer into the compounded admixture. This leak would be most noticeable when the EXACTAMIX Compounder is pumping and moving fluid through the common fluid pathway. The affected product has been distributed since 9/16/2021 in the United States.

Affected Product

Product Code	Product Description	Lot Number	Expiry Date	UDI Number
H938724	EXACTAMIX 2400 Valve Set	Lot 60316024 and higher	Beginning with 04/30/2024	00085412477183

Hazard Involved

The leaking valve set could result in a patient receiving an incorrect final admixture in terms of the prescribed constituents or there may be an administration delay related to the need to recompound the admixture. Additional hazards that may result include excessive or insufficient therapy, incorrect concentration or strength, incorrect product administered, and precipitate formation. To date, there have been no reports of serious injury.

Actions to be Taken by Customers

Baxter currently has significant supply constraints for our EXACTAMIX Valve Sets required for the EXACTAMIX Automated Compounding Device. Therefore, we are recommending the following actions:

1. **Please call Baxter at 888-608-9898**, between the hours of 8:00 am and 7:00 pm Eastern Time, Monday through Friday, to **schedule an appointment for a device correction** that will add new compounder configurations. You will require setup of new compounder configurations that omit the use of ports 1-4, and only use ports 5-24 for the ingredients on your compounder. During the device correction period, a maximum of 20 ingredients will be able to be pumped via the compounder.

2. Customers may continue compounding with affected valve sets during the device correction period, including any valve sets that were set aside by customers pending Baxter's investigation of this leak issue, provided those valve sets have remained in their original unopened packages, were stored in accordance with the instructions for use, and are not expired.

   Baxter recommends customers observe the pumping process to monitor for leaks. Leaks have been reported on ports 1 and 2 when in the closed position, where standard EXACTAMIX configurations have lipids (white opaque colored) and multi-vitamin (yellow colored) ingredients. Additionally, port 3 is also designated for multi-vitamin ingredients. Baxter recommends customers observe the pumping process to ensure they do not see unintended white or yellow discolored solution pumping through the valve set tubing into the final container. If unintended transfer of solutions from ports 1-4 are noted during the compounding process, the user should abort the compounding process, discard the final container, replace the valve set, and report

the incident to Baxter Product Surveillance. Depending on the ingredients on ports 1-4 and the respective volumes, customers may be able to add these ingredients as manual additions. Consideration needs to be made for the type of ingredient to ensure there is no risk of precipitation based on the sequence of those additions.

Customers should continue to follow their institutional policy and procedures for compounding. The use of a 1.2-micron filter is a recommended best practice by ASPEN when administering all parenteral nutrition formulations.

3. **DO NOT** attempt to add new compounder configurations on your own due to the complexity of the process and potential patient safety concerns if not done correctly. Serious injuries may result to patients due to incorrect, excessive, or insufficient product in the compounded bag if configured incorrectly.

4. Once Baxter has implemented corrective actions to resolve the valve set leak issue, a follow-up notification will be sent to customers to provide additional instructions.

5. **If you received this communication directly from Baxter, please acknowledge receipt of this communication by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com, even if you do not have any 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 acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

6. If you purchased this product from a distributor, 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.

7. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

8. 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, contact Baxter Corporate Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

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

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to 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 online at: https://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 thank you for your attention to this important safety information.

Sincerely,

Kim Killackey
Vice President, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form Instruction Sheet