URGENT MEDICAL DEVICE CORRECTION

FOLLOW-UP: Baxter EXACTAMIX Valve Set Port Leakage

June 28, 2023

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

Problem Description

On July 14, 2022, Baxter issued an Urgent Medical Device Correction communication regarding the potential for leaking valves in the EXACTAMIX 2400 Valve Sets. Baxter had 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. To mitigate this issue, customers were provided with instructions for setting up a new compounder configuration that omitted the use of ports 1-4 until corrective actions were implemented.

Resolution

Baxter has implemented actions to correct the potential for leaking valves in the EXACTAMIX 2400 Valve Sets, including the deployment of new molding equipment and an improved assembly process. Customers may return to using all 24 ports on their compounders when using the newly manufactured EXACTAMIX 2400 Valve Sets (**product code H938724, lot 60459942 and sequentially higher**). Please note, if using valve sets with lot numbers that are sequentially lower than **60459942 (e.g., 60459941)**, you must continue to follow the configuration instructions that omit the use of ports 1-4.

Affected Product

Product Code	Product Description	Lot Numbers	Expiry Date	UDI Number
H938724	EXACTAMIX 2400 Valve Set	60316024 to 60459941	4/30/2024 to 1/31/2026	00085412477183

Hazard Involved

A leaking valve set could result in a patient receiving an incorrect final admixture in terms of the prescribed constituents, or there may be a delay in therapy related to the need to re-compound 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

1. Baxter is working to produce new valve sets as quickly as possible; however, you may still receive valve sets that were produced prior to the implementation of the corrective actions. To prevent a valve set shortage, customers should continue using valve sets in their inventories.
2. Continue using the compounder configuration that omits the use of ports 1-4 until you receive valve sets with product lot number **60459942, or sequentially higher.** Once your inventory is depleted of lot numbers **60459941** or lower, you may begin using all 24 ports of your compounder.

Lot Number(s)	Port Configuration
60459942 and higher	Can use all 24-ports
60459941 and lower	Must use 20-ports only, omitting ports 1-4

3. The 24-port configuration should already be available on the compounder. When this Device Correction was originally issued, the Baxter Technical Service and Medical team members worked with each customer to establish a 20-port configuration for temporary use. The original 24-port configuration should still be available on your ExactaMix configuration menu drop-down

Baxter is a registered trademark of Baxter International Inc.

list. If for some reason it is no longer available, please reach out to Baxter Technical Support at 800-678-2292, between the hours of 8:00 am and 7:00 pm Eastern Time, Monday through Friday, for assistance in establishing/restoring a 24-port configuration for compounding.

4. **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.
5. 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.
6. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
7. 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 follow-up 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 Technical Services at 800-678-2292, between the hours of 8:00 am and 7:00 pm Eastern 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 by emailing the complaint mailbox 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 patience on this matter and your attention to this important safety information.

Sincerely,

Kim Killackey
Vice President, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form Instruction Sheet

Baxter is a registered trademark of Baxter International Inc.