Urgent Medical Device Recall

August 9, 2022

Dear Directors of Pharmacy, Nursing, Oncology and Risk Management:

Problem Description

Baxter Healthcare Corporation is issuing an Urgent Medical Device Recall to the user level for the CLEARLINK solution sets listed below due to an increase in customer reports of leaks. The affected product was distributed to customers beginning on 10/14/2020 in the United States.

Baxter does not have replacement solution sets for product code 2R8403 and currently has limited supply of non-DEHP alternative solution sets. Baxter infusion pumps are calibrated for use solely with Baxter proprietary IV sets. Customers who are not experiencing leak complications should continue to use their solution sets according to the guidance provided below. Customers who are experiencing leak complications should immediately stop use of the affected leaking product.

Product codes 2R8401 and 2R8875 are alternative non-DEHP solution sets and are available in limited quantities. Product code 2C8401 is also an available alternative DEHP solution set and may be used if clinically acceptable.

Affected Product

Product Code	Product Description	Lot Number	UDI Number
2R8403	CLEARLINK Basic Solution Set with Duovent	All lots within expiry	00085412656649

Hazard Involved

These solution sets are commonly used for the delivery of hazardous drugs. A leaking solution set could result in exposure of healthcare personnel, patients and others to potentially hazardous/toxic or irritant substances. Additional hazards that may result include insufficient therapy, breach of the sterile fluid pathway possibly causing infusion of contaminated fluid, delay/interruption of therapy, and air ingress into the solution set. There have been no reports of serious injury related to this issue.

Actions to be taken by Customers

1. If **no** solution set leaks have been experienced, monitor the use of impacted solution sets closely (including during priming of the administration set and during bedside use) for issues as previously stated.
2. If any solution set leaks **are** experienced, cease use of the affected product and contact Baxter Corporate Product Surveillance at 800-437-5176 to report the complaint and to arrange for safe return of the product for further investigation. The product code and lot number can be found on the individual product pouch and carton. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.
3. If you have unused solution sets that you would like to return, contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.

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4. Once Baxter has implemented corrective actions to resolve the 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 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 conduct a consumer-level recall of the affected product that you distributed to customers 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 apologize for any inconvenience this may cause you and your staff.

Sincerely,

Rodrigo Montanez
Director, Product Quality
Baxter Healthcare Corporation

Enclosure: Reply Form Instruction Sheet