



FOR IMMEDIATE RELEASE

## BAXTER ISSUES URGENT MEDICAL DEVICE RECALL OF CLEARLINK SOLUTION SET 2R8403 DUE TO POTENTIAL RISK OF LEAKING COMPLICATIONS

DEERFIELD, Ill., AUG. 11, 2022– Baxter International Inc. announced today it has issued an Urgent Medical Device Recall of **Clearlink** Solution Set 2R8403 due to an increase in customer reports of leaks. The affected product was distributed to customers beginning on Oct. 14, 2020, in the United States. Baxter communicated about this issue to customers via an [Urgent Medical Device Recall notification](#) on Aug. 9, 2022.

### Affected Product Code

Product Code	Product Description	Lot Number	UDI Number
2R8403	<b>Clearlink</b> Basic Solution Set with Duovent	All lots within expiry	00085412656649

While there have been no reports of serious injury related to this issue, **Clearlink** Solution Sets are commonly used for the delivery of hazardous drugs. A leaking solution set could result in healthcare personnel, patients and others being exposed to potentially hazardous, toxic, or irritant substances. Additional potential hazards may include insufficient therapy, breach of the sterile fluid pathway and infusion of contaminated fluid, delay or interruption of therapy and air ingress into the solution set.

Due to the limited supply of non-di(2- ethylhexyl) phthalate (nDEHP) alternatives, product code 2R8403 will continue to be manufactured and distributed. nDEHP alternatives will be available in limited quantities and a DEHP alternative is available if clinically acceptable. Additionally, Baxter’s infusion pumps can only be used with the company’s proprietary IV sets. Therefore, customers who are not experiencing leak complications should continue to use **Clearlink** Solution Sets according to the guidance provided in Baxter’s Urgent



Medical Device Recall notification, while monitoring the use of impacted solution sets closely for issues (including during priming of the administration set and during bedside use).

Customers who are experiencing leak complications should immediately cease use of the affected product and contact Baxter Corporate Product Surveillance at 800-437-5176 to report the issue and arrange for safe return of the product for further investigation. Customers that would like to return unused solution sets should contact Baxter Healthcare Center for Service at 888-229-0001 between the hours of 7:00 a.m. and 6:00 p.m. Central Time, Monday through Friday, to arrange for return and credit. All customers calling Baxter Product Corporate Surveillance or Baxter Healthcare Center for Service should have their Baxter eight-digit ship- to account number, product code, lot number and quantity of product to be returned ready. The product code and lot number can be found on the individual product pouch and carton. Once Baxter has implemented corrective actions to resolve the issue, a follow-up notification will be sent to customers to provide additional instructions.

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 a.m. and 5:00 p.m. Central Time, Monday through Friday.
- Emailing to Baxter at: [corporate\\_product\\_complaints\\_round\\_lake@baxter.com](mailto: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](http://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.

Baxter is voluntarily issuing this Urgent Medical Device Recall with the knowledge of the U.S. Food and Drug Administration.

#### **About Baxter**



Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit [www.baxter.com](http://www.baxter.com) and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

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