BD Issues Nationwide Recall for Specific Lots of ChloraPrep™ Clear Single Sterile 1 mL and FREPP™ Clear 1.5 mL Applicators Due to Microbial Contamination

FRANKLIN LAKES, N.J. (June 06, 2026) – BD (Becton, Dickinson and Company) is voluntarily recalling lot 4032183 of ChloraPrep™ Clear 1 mL Single Sterile and lot 4073005 of FREPP™ Clear 1.5 mL applicators with paper lidding to the consumer level. These products are being recalled due to fungal contamination under certain environmental conditions allowing the growth of Aspergillus penicillioides.

These two impacted lots were shipped to distributors and hospitals between March 2024 through June 2024.

Risk Statement: Contamination of skin preparation products with Aspergillus penicillioides may lead to serious systemic infection, sepsis, illness, and death. If the fungus is introduced in the patient's bloodstream during placement of an intravascular catheter, the catheter would most likely have to be removed, necessitating another procedure. Aspergillus penicillioides infection of a surgical site may result in the need for medical and surgical interventions and long-term treatment with antifungal drugs. Importantly, BD has not received any reports of adverse events related to this recall.

Affected Product NDC	Product Name	Catalog (REF) Number	Lot Number	Expiry Date	Product Package Size
54365-400-31	BD ChloraPrep™ Clear - 1 mL Applicators	930480	4032183	01/31/2027	60 Applicators per Inner Carton
54365-400-30	BD ChloraPrep™ FREPP™ Clear 1.5 mL Applicators	930299	4073005	03/31/2027	20 Applicators per Inner Carton

In addition, BD is recalling other lots out of an abundance of caution as outlined in the customer letter.

These products are packaged in a pouch with paper lidding and used for the preparation of the patient's skin prior to procedures, to help reduce bacteria that potentially can cause skin infection.

The affected lots can be identified by locating the referenced catalog and lot numbers on the lidding of the product package and the side of the inner carton as shown in the customer letter.

BD is notifying its customers and distributors who received this product directly. Customers and distributors should immediately discontinue use of and destroy all affected units in accordance with their facility's process.

BD will issue replacement for destroyed product of the affected lot numbers to customers that purchased the affected product directly from BD, following receipt of the completed Customer Response Form.

Customer inquiries related to this recall, as well as adverse reaction/events experienced with the product, should be addressed to BD's North American Regional Complaint Center: 1-844-823-5433 (Toll Free) Monday – Friday between the hours of 8a.m. and 5 p.m. CT or by emailing: productcomplaints@bd.com.

FDA MedWatch Reporting

Adverse reactions/events experienced with the use of any of these products should also be reported to the FDA's MedWatch Adverse Event Reporting program either online, phone or by regular mail.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Call** 1-800-FDA-1088 (1-800-332-1088)
- **Regular Mail**: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

The U.S. Food and Drug Administration (FDA) has been notified of this recall.

About BD

BD is one of the world's largest pure-play medical technology companies with a Purpose of *advancing the world of health™* by driving innovation across medical essentials, connected care, biopharma systems and interventional. The company supports

those on the frontlines of healthcare by developing transformative technologies, services and solutions that optimize clinical operations and improve care for patients. Operating across the globe, with more than 60,000 employees, BD delivers billions of products annually that have a positive impact on global healthcare. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase clinical efficiency, improve safety and expand access to healthcare. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X @BDandCo or Instagram @becton_dickinson.

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