

BD Expands Voluntary Recall of Chloraprep™ 3 mL Applicator Nationwide to Include All U.S. States

FRANKLIN LAKES, N.J. (March 24, 2021) – BD (Becton, Dickinson and Company), a leading global medical technology company, has revised its press release dated March 19, 2021 relating to an expanded voluntary recall that was initiated on June 23, 2020 for specified catalog numbers of the Chloraprep™ 3 mL applicator due to possible fungal contamination under certain environmental conditions.

BD has determined that storage of the Chloraprep™ 3 mL Applicator in regions of the world with high heat and humidity, where product may be exposed to temperatures of 30 degrees Celsius (86 degrees Fahrenheit) and 75% relative humidity, allows the growth of *Aspergillus penicillioides*.

The *Aspergillus penicillioides* within the packaging can contaminate the surface of the applicator and/or gloved hands of the health care professional and then consequently the sterile field. Since the applicator is used for site preparation prior to an invasive procedure, a contaminated applicator can result in direct inoculation of the fungus into tissues. To date, no complaints, adverse events, injuries, or deaths have been reported related to this voluntary recall.

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.

This recall does not include 3 mL applicators found in kits. It also does not include any other Chloraprep™ product presentations. All other Chloraprep™ products are manufactured with different packaging materials that are not affected by this issue. BD is implementing a global packaging change for the 3 mL product to correct this issue, which is expected to be available by the end of April in the United States. The implementation time for other countries will vary based on registration requirements.

As part of the voluntary recall to the user level, the company will notify customers and distributors affected by the recall. BD is instructing customers and distributors to discard all remaining inventory of the impacted Chloraprep™ 3 mL applicators (see list of impacted catalog numbers below) and committed to replacing product affected by the recall.

Affected Catalog Numbers in the United States	
260400	Chloraprep® One-Step 3 mL Applicator - Clear
260415	Chloraprep® One-Step 3 mL Applicator - Hi-Lite Orange
930400	BD Chloraprep™ Clear 3 mL Applicator
930415	BD Chloraprep™ Hi-Lite Orange™ 3 mL Applicator

Customer inquiries related to this recall, as well as adverse reaction/events experienced with the product should be addressed to BD Customer Support: 1-800-526-4455 (Toll Free) between the hours of 8:30 a.m. and 6 p.m. ET.

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, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com](https://www.bd.com) or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter [@BDandCo](https://twitter.com/BDandCo).

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