BD Announces Voluntary Recall of ChloraPrep™ 3 mL Applicator in Specific U.S. Territories and Countries

FRANKLIN LAKES, N.J., Aug. 7, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company), a leading global medical technology company, announced a voluntary recall on June 23, 2020 for specified catalog numbers of the ChloraPrep™ 3 mL applicator due to possible fungal contamination, which only affects climate zone IV regions in specific U.S. territories and countries (see list of catalog numbers and regions impacted by this issue below).

BD has identified that storage of the ChloraPrep™ 3 mL Applicator in regions of the world with high heat and humidity, where product may be consistently exposed to temperatures of 30 degrees Celsius (86 degrees Fahrenheit) and 75% relative humidity for more than six months, may result in the growth of *Aspergillus penicillioides*. **The recall does not apply to any states in the United States**, it only applies to the U.S. territories of Puerto Rico, Guam, U.S. Virgin Islands, Northern Mariana Islands and American Samoa.

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.

As part of the voluntary recall to the user level, the company notified customers and distributors affected by the recall and provided guidance on the potential impact when the affected products were used.

Through internal product quality testing, BD has identified that storage of the ChloraPrep™ 3 mL Applicators where product may be consistently exposed to temperatures of 30 degrees Celsius (86 degrees Fahrenheit) and 75% relative humidity for more than six months can result in the growth of *Aspergillus penicillioides*, a type of fungus, resulting in a breach in the outer package integrity.

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. Contamination of skin preparation products with *Aspergillus penicillioides* may lead to serious systemic infection, sepsis, illness and death. If the fungus is introduced into 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.

To date, no complaints, adverse events, injuries or deaths have been reported related to this voluntary recall.

At the time of the recall, BD informed customers and distributors in the affected territories 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 U.S. Territories/Countries	
American Samoa	Nicaragua
Bahrain	Northern Mariana Islands
Brazil	Oman
Colombia	Panama

Costa Rica	Paraguay
El Salvador	Puerto Rico
Guam	Qatar
Guatemala	Saudi Arabia
Hong Kong	Singapore
India	United Arab Emirates
Kuwait	U.S. Virgin Islands

Affected Catalog Numbers in U.S. Territories	
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

This recall is limited to the U.S. territories and countries listed above. This recall does not affect any other ChloraPrep™ product presentations, regardless of geography.

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 65,000 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.

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