

### FDA Recall – BD ChloroPrep Clear & FREPP Clear Applicators

#### Purpose of this communication:

We are writing to inform you that BD has issued a nationwide recall for specific lots of ChloroPrep Clear 1 mL Single Sterile and FREPP Clear 1.5 mL applicators with paper lidding due to potential fungal contamination. The impacted products include lot 4032183 of ChloroPrep Clear 1 mL Single Sterile and lot 4073005 of FREPP Clear 1.5 mL applicators, which were shipped to distributors and hospitals between March 2024 and June 2024.

BD identified that, under certain environmental conditions, the affected lots may allow the growth of *Aspergillus penicillioides*. Contamination of skin preparation products with this fungus may lead to serious systemic infection, sepsis, illness, or death. If introduced into a patient's bloodstream during intravascular catheter placement, the catheter would likely need to be removed and replaced. Surgical site infection may require medical or surgical intervention and long-term antifungal treatment. As of the recall notice, BD has not received any reports of adverse events related to this issue.

#### What do I need to do?

- Please review the [FDA recall notice](#).
- Notify impacted patients to immediately discontinue use of and destroy all affected units in accordance with their facility's process according to the guidelines issued by the manufacturer in the FDA notification. 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.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.