



## BD – Recall of ChloroPrep™ Hi-Lite Orange™ (chlorhexidine gluconate/isopropyl alcohol)

- On April 20, 2021, [BD announced](#) a voluntary, user-level recall of specific lots of [ChloroPrep Hi-Lite Orange](#) 26 mL applicator (2% w/w chlorhexidine gluconate and 70% v/v isopropyl alcohol) due to a defective applicator.
  - ChloroPrep products that are not being recalled are available for patients to use.
- Refer to the [BD announcement](#) for the list of recalled lots.
- ChloroPrep Hi-Lite is used as an antiseptic for the preparation of the patient's skin prior to surgery to help reduce bacteria that potentially can cause skin infection.
- The ChloroPrep applicator contains glass ampules that house the sterile ChloroPrep solution. The product is activated by squeezing the wing on the applicator to break the ampule, which releases the solution to the sponge head for application to the patient's skin.
- In the recalled lots, the applicator end cap was improperly secured due to a manufacturing error. This can result in broken glass and solution dropping out of the applicator once activated. In some cases, the glass ampules can drop out before activation and shatter if striking a hard surface, resulting in solution and glass fragments scattering in the procedure area and potentially causing injury to patients and healthcare providers.
  - Health consequences could be superficial to deep lacerations to patient and/or user of the device that may lead to infection and scarring.
  - “Flying” glass shards or splashing ChloroPrep solution could potentially cause injury to the patient or user, including eye, skin, tissue or organ injuries. Blood loss may even occur.
- To date, BD has received 56 complaints with only one laceration injury reported with respect to the defective applicators.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled ChloroPrep product.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- Contact BD Customer Support by phone at **1-844-823-5433** for more information about this recall.



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