Elevating the standard

NEW BD ChloraPrep™ patient preoperative skin preparation with sterile solution

Advancing health by assuring product sterility

- BD ChloraPrep™ patient preoperative skin preparation has been used in hospitals for more than 18 years, delivering effective skin antisepsis
- Now, this long-trusted product is the only FDA-approved, commercially available patient preoperative CHG antiseptic solution in the United States that is sterilized during the manufacturing process

Providing peace of mind for patients, clinicians and risk management

- Sterilizing the antiseptic solution during production can minimize potential intrinsic bacterial threats
- However, most U.S. manufacturers of commercially available antiseptic skin preparations have not adopted this technologically challenging process
- BD tackled the challenge, developing a patented sterilization process designed to provide sterility assurance

With FDA-approved BD ChloraPrep™ patient preoperative skin preparation with sterile solution, BD has taken antiseptic sterility assurance to a different level

STERILE SOLUTION™

BD

Going beyond what is required to do what is right

Antiseptic solutions don't self-sterilize

- According to the FDA, intrinsic contamination "may occur during the manufacturing process"[1]
- Infections from intrinsic contamination of antiseptics have been documented[2,3]
- Because of intrinsic contamination risks, the FDA requested that manufacturers label topical antiseptic solutions as sterile or nonsterile[1]

BD has done more than change the label

- BD ChloraPrep™ patient preoperative skin preparation has not previously been associated with intrinsic contamination issues
- Nonetheless, BD invested more than 6 years and significant resources to develop the **only commercially available chlorhexidine gluconate-based, sterile solution antiseptic skin preparation product in the United States**

The BD breakthrough sterilization process raises the standard

Maintains the **efficacy and purity** of the antiseptic solution[4]

Less than a **1 in 1 million** chance that a viable micro-organism can exist in a BD ChloraPrep™ applicator[4]

Sterility assurance level of 10^{-6}
The same level required for injectable products[4]

BD ChloraPrep™ patient preoperative skin preparation with sterile solution: elevating the standard in preoperative skin antisepsis

To learn more, visit **bd.com/ChloraPrepSterileSolution** or call **800-523-0502**

References

1 Food and Drug Administration. FDA Drug Safety Communication: FDA requests label changes and single-use packaging for some over-the-counter topical antiseptic products to decrease risk of infection. https://www.fda.gov/drugs/drugsafety/ucm374711.htm. **2** Chang C, Furlong LA. Microbial stowaways in topical antiseptic products. *N Eng J Med.* 2012;367;23:2170-2173. doi: 10.1056/NEJMp1212680. **3** Weber DJ, Rutala WA, Sickbert-Bennett EE. Outbreaks associated with contaminated antiseptics and disinfectants. *Antimicrob Agents Chemother.* 2007;51(12):4217-4224. doi:10.1128/AAC.00138-07. **4** Degala, et al. United States Patent 9,078,934. July 14, 2015.

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