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BD Receives FDA Approval for Fully Sterile Chlorhexidine Gluconate Antiseptic Skin Preparation

New BD ChloraPrep™ Skin Preparation is the Only Commercially Available CHG Antiseptic Skin Preparation with Sterile Solution Designation in the U.S.

FRANKLIN LAKES, N.J., April 30, 2019 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has received U.S. Food and Drug Administration (FDA) approval for BD ChloraPrep™ skin preparation with sterile solution, the only fully sterile chlorhexidine gluconate (CHG) antiseptic skin preparation commercially available in the U.S.

This new BD ChloraPrep™ product uses a proprietary and patented process to sterilize the antiseptic solution inside the sealed ampoules located in the BD applicator. With the new sterilization process in place, the BD ChloraPrep™ solutions portfolio that undergo this proprietary added level of sterility will now be labeled as a "sterile solution" on all packaging.

"At BD, we are constantly exploring new opportunities to protect patients and advance health," said Michael Garrison, worldwide president of Surgery at BD. "The FDA approval of BD ChloraPrep antiseptic skin preparation with sterile solution ensures that the solution inside of the applicator receives the same level of sterilization as the applicator itself to help further reduce the risk of intrinsic contamination."

Following FDA hearings in 2012 focused on sterility of skin antiseptic products and subsequent label changes in 2013, BD determined to proactively address the sterilization challenge in the U.S. Over the last six years, BD has invested in the development of an innovative sterilization process that not only can handle the volume of product demanded, but also improves overall efficiency versus traditional sterilization methods.[1]

"The idea of contaminated antiseptic solutions seems counter-intuitive because the function of an antiseptic is to kill bacteria," said Donald E. Fry, M.D., a nationally recognized expert in infection prevention. "Outbreaks of highly resistant bacteria and spore contamination have been reported with contaminated antiseptic products in the past. Now with a fully sterilized

skin preparation product, BD is assisting health care providers with a tool to enhance patient safety by the reduction of risk from intrinsic contamination in antiseptic solutions."

Novel Sterilization Process

BD's proprietary sterilization process was designed to achieve a minimum sterility assurance level (SAL) of 10^{-6}, the same level required for injectable products.[1] The SAL indicates there is less than 1 in 1 million chance that a sterile BD ChloraPrep™ applicator containing sterile solution will contain a single, viable microorganism following terminal sterilization of the ampoules through BD's new sterilization process.[1] While a product labeled as non-sterile does not suggest that it is contaminated with bacteria, it indicates that the contents have not been sterilized individually. Traditionally, BD ChloraPrep™ applicators have been sterilized at the end of the manufacturing process and the solution inside of the applicators was not treated with a separate sterilization process. This new process adds another layer of assurance to an already-proven product and builds on the heritage and reliability of BD ChloraPrep™ skin preparation.

The new BD ChloraPrep™ sterile solution will include a mark to indicate that it is sterile. Though not required by the FDA, BD developed this mark to distinguish sterile solution from non-sterile antiseptic skin preparations. In 2013, the FDA asked manufacturers to voluntarily change labeling on products (sterile vs. non-sterile) to further educate customers on the issue.

As a leader in antiseptic skin preparation and patient pre-operative skin preparation, BD is continually working to improve technology and patient safety. BD ChloraPrep™ skin preparation continues to be the leading standard of care for preoperative antiseptic skin preparations. Since its introduction over 18 years ago, more than four billion applicators have been used. BD ChloraPrep™ skin preparation, and its efficacy, is supported by more than 50 clinical publications.

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.

[1] Degala, et al. United States Patent 9,078,934. July 14, 2015.

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