

Confident efficacy. Full sterility.

BD's extensive line of sterile patient preoperative skin preparation products raises the standard.



Significant challenges, important choices

Healthcare-associated infections (HAIs) are a major concern for hospitals everywhere



The human and economic toll of HAIs

In the United States, **687,000 HAIs** in a single year¹ As many as ~**75,000 deaths** annually² Nearly **\$10 billion** in annual costs³

HAI risks have led healthcare professionals to take a close look at preoperative skin preparation

• Alcohol-based preoperative skin antiseptics are recommended in the latest evidence-based infection guidelines published by preeminent health organizations:



World Health Organization (WHO): The panel recommends alcohol-based antiseptic solutions based on chlorhexidine gluconate (CHG) for surgical skin site preparation. (2016)⁴

American College of Surgeons/Surgical Infection Society (ACS/SIS): Alcohol-containing preoperative skin preparatory agents unless contraindication exists. (2016)⁵



Centers For Disease Control and Prevention (CDC): Perform intraoperative skin preparation with an alcohol-based antiseptic agent unless contraindicated. (2017)⁶

HAI risks due to intrinsic antiseptic contamination led the FDA to take action

- Non-sterile preoperative skin antiseptics run the risk of intrinsic contamination during manufacturing⁷
- Infectious outbreaks from intrinsic contamination have resulted in morbidity and mortality^{8,9}
- Because of this risk, the Food and Drug Administration (FDA) requested that preoperative skin antiseptics be labeled as sterile or non-sterile to allow for informed decisions⁷

"In past years, outbreaks associated with the use of contaminated topical antiseptics have led to some product recalls...."⁷

- FDA Drug Safety Communication

BD has the solutions

High-quality products backed by highly qualified professionals

A portfolio of alcohol-containing, sterile antiseptic products

Chlorhexidine gluconate/Isopropyl alcohol BD ChloraPrep[™] Patient Preoperative Skin Preparation with Sterile Solution



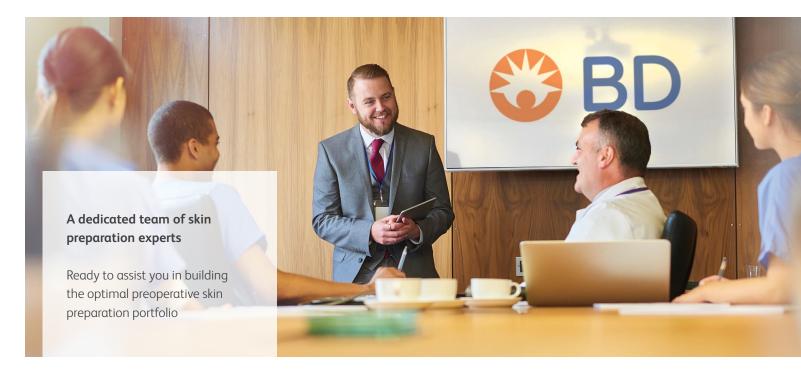
Elevating the standard in skin antiseptic sterility

An effective alternative when a chlorhexidine gluconate plus alcohol is not ideal BD PurPrep^M Patient Preoperative Skip Preparation with

BD PurPrep[™] Patient Preoperative Skin Preparation with Sterile Solution

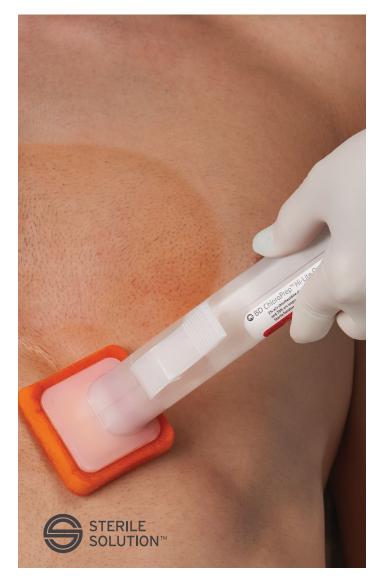


Sterile. Simple. Effective.



Advancing patient safety through product sterility

BD has achieved a breakthrough in antiseptic sterilization



Sterilizing antiseptic solutions is a difficult challenge

- Some manufacturers have asserted that it is "impossible or impractical"¹⁰
- Conventional terminal sterilization processes such as high heat and radiation are not compatible with some common antiseptics, including CHG^{10,11}
- Can compromise the chemical integrity of the active ingredient¹⁰

BD overcame the "impossible"¹⁰

• Putting patient safety first, BD committed significant time and resources to develop patented sterilization technology¹²

The lowest risk of intrinsic contamination available in the United States

• BD's sterilization technology delivers 1,000 times the required minimum sterility assurance¹²

Maintains the **efficacy and purity** of the antiseptic solution¹²

Less than 1-in-a-million chance that a viable microorganism can exist in a BD ChloraPrep[™] product¹²

Sterility assurance level of 10⁻⁶—the same level required for injectable products¹²

The commitment behind the achievement



6 years







A winning combination for complete sterility

BD's sterile antiseptics come in proprietary sterile applicators that help prevent extrinsic contamination⁷

Designed to improve antiseptic application

• Eliminates variability to help make life easier for clinicians and ensure a consistent, appropriate technique for patients

Single step As easy as "Pinch. Apply. Let Dry."

Single handed Does not require burdensome

two-handed technique

Single use

Helps reduce risk of cross-contamination with no ability to manipulate the solution⁷



BD ChloraPrep[™] Patient Preoperative Skin Preparation with Sterile Solution

Elevating the standard in sterile preoperative skin antisepsis



The only CHG-based, sterile solution antiseptic skin preparation product commercially available in the United States

- A dual formulation of 2% CHG and 70% isopropyl alcohol (*IPA*)
- Comes ready to use in a proprietary sterile applicator for even greater peace of mind
- Broad spectrum, rapid, persistent antimicrobial activity for at least 48 hours¹³⁻¹⁵

Meets FDA requirements for antimicrobial activity^{15,16}

In the abdomen

Achieves a 2-log reduction in microbial flora per square centimeter $^{15}\,$

In the groin

Achieves a 3-log reduction in microbial flora per square centimeter $^{\rm 15}$



Reductions within 10 minutes¹⁵



Maintained for 48 hours¹⁵



Backed by more than 50 studies

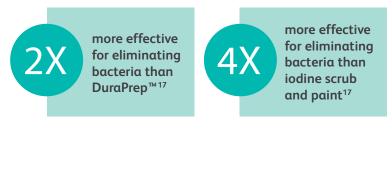
- Studied more than any other skin antiseptic brand*
- Offers unsurpassed evidence of consistently dependable efficacy and safety*
 * Data on file.



Trusted by hospitals for more than 18 years

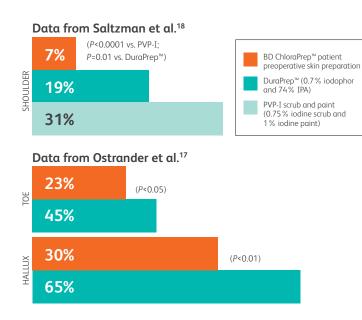
- Supported by evidence-based guidelines published by the WHO, CDC, and ACS/SIS⁴⁻⁶
- More than 4 billion applicators used to date

Superior antimicrobial performance vs. iodine- and alcoholbased products^{17,18}



Significantly lower positive culture rates vs. PVP-I and $\text{DuraPrep}^{^{\rm {\tiny M}17,18}}$

Results from two prospective, randomized studies (*level 1 evidence*)







"The potential properties that make chlorhexidine highly effective are a strong affinity for binding to the skin, high antibacterial activity, and prolonged residual effects."¹⁸

- Saltzman et al, The Journal of Bone and Joint Surgery

BD ChloraPrep[™] Patient Preoperative Skin Preparation with Sterile Solution

Unparalleled flexibility for your wide range of patients and procedures

Lets you tailor your choice to the surface area, type of site, and skin color

• Allows for standardized skin preparation and associated cost savings



Hi-Lite Orange[™] For lighter pigmented skin Scrub Teal[™] For darker pigmented skin When you want a colorless effect

Can be used with or without a drape

• When allowed to fully dry per the DFU, BD ChloraPrep provides effective drape utilzation

Available in all surgical packs and through all distribution partners

• Providing exceptional convenience to accommodate your varying surgical needs

Make your own comparisons

See how your preoperative skin antiseptic stacks up

Attribute	IPA	Iodophors (iodine-based)	CHG	Iodine + IPA	CHG + IPA	BD ChloraPrep™ with Sterile Solution
Broad spectrum ¹⁹⁻²²	1	<i>✓</i>	1	1	1	✓
Fast acting ¹⁹⁻²²	1			1	1	✓
Persistent ¹⁹⁻²²			1	1	1	✓
Sterile solution						✓

Ordering information

	Applicator	SKU#	Quantity
<i></i>	1 mL clear	930480	60 app/carton 4 cartons/case
<i>i</i>	Frepp™ 1.5 mL clear	930299	20 app/carton 25 cartons/case
	3 mL clear	930400	25 app/carton 4 cartons/case
P	3 mL Hi-Lite Orange™	930415	25 app/carton 4 cartons/case
and the second s	10.5 mL clear	930700	25 app/carton 4 cartons/case
	10.5 mL Hi-Lite Orange™	930715	25 app/carton 4 cartons/case
	10.5 mL Scrub Teal™	930725	25 app/carton 4 cartons/case
	26 mL clear	930800	25 app/case
	26 mL Hi-Lite Orange™	930815	25 app/case
	26 mL Scrub Teal™	930825	25 app/case

BD PurPrep[™] Patient Preoperative Skin Preparation with Sterile Solution

A sterile, simple, and effective alternative when a CHG + alcohol solution is not ideal



Ordering information

The first and only fully sterile iodine-based skin prep applicator available in the United States

- A dual formulation of PVP-I (0.83% available iodine) and 72.5% IPA
- In clinical studies, PVP-I has demonstrated broad spectrum antimicrobial properties²³
- Comes ready to use in a proprietary sterile applicator for even greater peace of mind
- An option when CHG is contraindicated or for patients with CHG allergies/sensitivities

Aligns with current preoperative skin prep guidelines from leading U.S. health organizations

• CDC and ACS/SIS recommendations support use of alcoholbased antiseptic formulations unless contraindicated^{5,6}

Designed to improve antiseptic application over standard scrub and paint methods ^{7,17,18}

Dual formulations are more effective at killing bacteria^{17,18}

Single-use applicator can shorten application times^{24,25}

Features a fluid-resistant, film-forming polymer that facilitates drape adhesion and easy removal²⁶

- Helps create a durable antimicrobial barrier²⁷
- Helps iodine bind to the skin for residual antimicrobial activity
- Facilitates drape adherence while permitting gentle drape removal
- Requires no separate remover—potentially reducing extra time and cost

Applicator	SKU#	Quantity
26 mL PurPrep™	960120	25 app/carton

BD: Your partner in preoperative skin prep

Personalized assistance and plentiful resources

A dedicated team of skin preparation experts who care about your success

- These highly trained specialists know our products inside and • out, as well as the current guidelines for preoperative skin prep
- They are available expressly for you to answer any product • questions you may have
- They can help to ensure the right BD product is being used at • the right time

A partnership that includes ongoing training and support

- In-service training and educational materials
- Can help to improve the standard of care for preoperative skin antisepsis in your operating room by working directly with your team to:





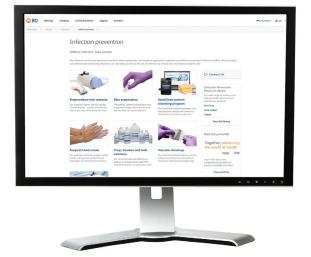
Identify and address practice gaps and process variability



Supports recommendations of current clinical standards and guidelines



Enhance clinician knowledge to help improve patient care



Our robust online resources are available for you 24 hours a day, 7 days a week, 365 days a year

www.bd.com/infectionprevention:

- To find out about more preoperative skin preparation tools
- To see the in-service video
- To contact sales and support
- To view product labels

References

1 Centers for Disease Control and Prevention. Healthcare-associated infections. https://www.cdc.gov/hai/data/portal/index.html. Accessed March 24, 2020. 2 Centers for Disease Control and Prevention. HAI data and statistics. https://www.cdc.gov/hai/surveillance. Accessed October 26, 2017. 3 Zimlichman E, Henderson D, Tamir O, et al. Healthcare-associated infections: a meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med. 2013;173(22):2039-2046. 4 World Health Organization. Global guidelines for the prevention of surgical site infection. Geneva, Switzerland. 2016. https://www. ncbi.nlm.nih.gov/books/NBK401132/pdf/Bookshelf_NBK401132.pdf. Accessed May 16, 2018. 5 Ban K, Minei JP, Laronga C, et al. American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. J Am Coll Surg. 2017;224(1):59-74. http://dx.doi.org/10.1016/j.jamcollsurg.2016.10.029. 6 Berríos-Torres SI, Umscheid CA, Bratzler DW. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. 2017;152(8):784-791. 7 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. Accessed March 19, 2019. 8 Dolan SA, Dowell E, Littlehorn C, et al. Contamination of alcohol prep pads with Bacillus cereus group and Bacillus species—Colorado, 2010. Centers for Disease Control and Prevention MMWR. 2011;60(11):347. 9 NBC News. Bacteria in antiseptic skin prep? FDA ponders sterility. December 5, 2012. http://vitals.nbcnews. com/_news/2012/12/05/15702729-bacteria-in-antiseptic-skin-prep-fda-ponderssterility? lite. Accessed May 6, 2019. 10 Pyrek KM. Sterility of antiseptic products: FDA investigates, deliberates on potential recommendations. Infection Control Today. 2013; July:1-30. https://brnskll.com/wpcontent/uploads/2013/12/FDAinvestigates-Antiseptics-Sterility-and-potential-recommendations.pdf. Accessed April 20, 2019. 11 Zong Z, Kirsch L. Studies on the instability of chlorhexidine, part I: Kinetics and mechanisms. J Pharm Sci. 2012;101(7):2417–2427. doi: 10.1002/jps.23151. 12 Degala, et al. United States Patent 9,078,934. July 14, 2015. 13 Denton GW. Chlorhexidine. In: Block SS. Disinfection, Sterilization, and Preservation. 5th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2001:321–336. 14 Larson E. Guideline for use of topical antimicrobial agents. Am J Infect Control. 1988;16(6):253-266. 15 Hibbard JS. Analyses comparing the antimicrobial activity and safety of current antiseptic agents: a review. J Infus Nurs. 2005;28(3):194-207. 16 Department of Health and Human Services, Food and Drug Administration. Safety and effectiveness of healthcare antiseptics; topical antimicrobial drug products for over-the-counter human use. 21 CFR Part 310. Federal Register. 2017;82(243):60474-60503. 17 Ostrander RV, Botte MJ, Brage ME. Efficacy of surgical preparation solutions in foot and ankle surgery. J Bone Joint Surg Am. 2005;87(5):980–985. 18 Saltzman MD, Nuber GW, Gryzlo SM, Marecek GS, Koh JL. Efficacy of surgical preparation solutions in shoulder surgery. J Bone Joint Surg Am. 2009;91:1949-1953. 19 Mangram AJ, Horan TĆ, Pearson ML, Silver LC, Jarvis WR. Infect Control Hosp Epidemiol. 1999;20(4):247-278. 20 AORN. Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc.; 2013:75-89. 21 Galvin P. Cultivating quality: reducing surgical site infections in children undergoing cardiac surgery. Am J Nurs. 2009;109(12):49-55. doi: 10.1097/01.NAJ.0000365187.47124.c0. 22 Karpanen TJ, Worthington T, Conway BR, Hilton AC, Elliott TSJ, Lambert PA. Antimicrob Agents Chemother. 2009;53(4):1717-1719. doi:10.1128/AAC.01289-08. 23 Hemani ML, Lepor H. Skin preparation for the prevention of surgical site infection: which agent is best? Rev Urol. 2009;11(4):190-195. doi: 10.3909/riu0467. 24 BD PurPrep[™] patient preoperation skin preparation with sterile solution IFU. 25 BD wet PVP-I small procedure preoperative skin prep tray IFU. 26 Mashiatulla, M. (2020). Iodine-based Pre-Operative Skin Preparation Product Performance on Porcine Abdominal Skin. Internal BD report: unpublished. 27 Jeng DK. A new, water-resistant, film-forming, 30-second, one-step application iodophor preoperative skin preparation. Am J Infect Control. 2001;29(6):370-376.

Learn more about BD skin preparation products at bd.com/chloraprepsterilesolution or call 1-844-8 BD LIFE (844-823-5433)

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bd.com





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