BD Surgiphor™ Antimicrobial Irrigation System

Ready-to-use and terminally sterile.
Every bottle. *Every* time.

Not all irrigation solutions are created equal

Unlike other off-the-shelf products, BD Surgiphor™ Antimicrobial Irrigation System is the **only pre-mixed, terminally sterile povidone-iodine (PVP-I) wound irrigation solution**. It delivers a dilute PVP-I lavage to mechanically loosen and remove debris and foreign materials, including microorganisms from wounds, during surgery. Here are some of the **key benefits you could offer your patients and team** with the BD Surgiphor™ Sterile Solution™:

Provides **99.99% reduction of bacteria** with PVP-I as a preservative in the solution*^,[1]

Kills Methicillin-resistant *Staphylococcus aureus* faster at all time points up to 5 minutes compared to the CHG preservative in Irrisept#,[2]

Reduces the risk of unwanted microbial growth in the solution **up to 24 hours** after the bottle is opened*^,[1]

Aligns with current guidelines from the CDC[3], WHO[4] and AAOS[5] to use dilute PVP-I for surgical wound irrigation

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Let's make sterility standard

The BD Surgiphor™ Antimicrobial Irrigation System with Sterile Solution™ has a **validated sterility assurance level (SAL) of 10^{-6}**—the same level required for injectable products and implantable devices.[†,6,7] So you can be confident that your wound irrigation solution has a **one in a million chance** of containing a single microorganism.

Simplify wound irrigation to control what you can in the OR

- **Reduce** variability in wound irrigation processes and practice
- **Improve** control, confidence and quality assurance
- **Standardize** formulation for your patients
- **Deliver** pressure within the range outlined by the AHCPR[8]

The BD Surgiphor™ **450 mL** compressible bottle contains **terminally sterile 0.5% PVP-I** formulation with Phosphate-buffered saline, Potassium Iodide and Vitamin E TPGS

SKU #: 910110

To order BD Surgiphor™ Antimicrobial Irrigation System, contact your BD sales rep

PVP-I is an antimicrobial preservative contained within the bottled solution. The Surgiphor solution is not indicated for use as an antimicrobial at or within the wound site.

CDC: Centers for Disease Control and Prevention; **WHO**: World Health Organization; **AAOS**: American Academy of Orthopaedic Surgeons; **AHCPR**: Agency for Health Care Policy and Research.

*At initial time point of 7 days. Product should be used only within 24 hours of opening per IFU. ˆPreservative solution with 0.5% PVP-I tested against *Candida albicans* (ATCC #10231), *Pseudomonas aeruginosa* (ATCC #9027), *Aspergillus brasiliensis* (ATCC #16404), *Escherichia coli* (ATCC #8739) and *Staphylococcus aureus* (ATCC #6538). #Shown by the in-vitro antimicrobial efficacy of the PVP-I preservative in the BD Surgiphor™ solution. †Sterility assurance level in accordance with ISO 11137.

Indication for use: Surgiphor™ Antimicrobial Irrigation System is intended to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds. **Contraindications:** Surgiphor™ Antimicrobial Irrigation System should not be used in patients with known allergic reaction to any of the ingredients in the solutions. Surgiphor™ Antimicrobial Irrigation System should also not be combined with other irrigation or antiseptic solutions due to potential reactions and reduction in the effectiveness of the system. Not for use in neonates. **Warnings:** Do not use or mix with other cleansers, soaps, lotions, or ointments. Do not use for injection or infusion. Do not swallow. Do not use in eyes or ear canals. Discontinue use immediately if irritation or an allergic reaction occurs. Do not use if packaging is damaged or if seal integrity is compromised. Do not reuse Surgiphor™ solution after 24 hours. **Precautions:** Surgiphor™ solution may cause a temporary irritation and/or burning sensation on exposed skin in very rare cases. Surgiphor™ solution may cause allergic reactions such as rash or skin irritation in patients with iodine allergy. Anaphylaxis with the use of Surgiphor™ solution may occur in patients with severe iodine allergy. Federal law restricts this device to sale by or on the order of a licensed physician. Single patient use only. Not for at-home use. Please consult product insert for complete indications, contraindications, warnings, precautions, safety information and instructions for use.

References

1. Surgiphor Solution Preservative Effectiveness Report. Orthopor LLC; 2019. **2.** Antimicrobial Efficacy Evaluation of 0.5% PVP-I and Irrisept® by In Vitro Time-Kill Assay. Internal report. Sidhu, P; 2021. **3.** Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection. *JAMA Surg.* 2017;152(8):784-791. doi: 10.1001/jamasurg.2017.0904 **4.** World Health Organization (WHO). Global Guidelines for the Prevention of Surgical Site Infection, 2nd edition. Geneva: World Health Organization; 2018. Accessed on September 6, 2022, at https://apps.who.int/iris/rest/bitstreams/1168437/retrieve. **5.** American Academy of Orthopaedic Surgeons (AAOS). Intraoperative Risk Factors. In Surgical Risk Reduction Toolkit. Accessed on September 6, 2022, at https://www.aaos.org/quality/quality-programs/quality-toolkits/prevention-of-surgical-site-infection/. **6.** Surgiphor Gamma Sterilization Validation Test Report. Orthopor LLC; 2019. **7.** Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST67:2019. Sterilization of health care products—Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile". Arlington: AAMI; 2019 **8.** Surgiphor System Mechanical Action Report. Orthopor LLC; 2019.

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