BD® Surgiphor™

Surgical Wound Irrigation System

The first and only CE approved, pre-mixed, terminally sterile, ready-to-use dilute PVP-I surgical irrigation system.

The BD Surgiphor™ Surgical Wound Irrigation System primary mode of action is to mechanically loosen and remove debris and foreign materials, including microorganisms from the surgical wound during surgery. The PVP-I serves as a preservative in the solution and provides an ancillary mode of action to further reduce bacterial load within the surgical wound.*,[1]

Terminally sterilized solution with a sterility assurance level (SAL) of 10^{-6}, providing confidence that the product has only a one in a million chance of containing a single viable microorganism.[1]

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

Provides a greater than 4log$_{10}$ reduction of bacteria in the bottle utilizing PVP-I as a preservative, and demonstrated a 2-4 log$_{10}$ bacterial reduction within the surgical wound.*,[1]

Consists of a pre-mixed and pre-labeled formulation that requires no mixing prior to use and aids in reducing potential risks associated with formulation variability and related medical errors.

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BD Surgiphor™

The only sterile PVP-I ready-to-use wound irrigation system

The BD Surgiphor™ Surgical Wound Irrigation System includes a 450 mL compressible bottle with terminally sterile 0.5% PVP-I formulation with 0.9% saline, Potassium Iodide, Phosphate Buffer, and Vitamin E TPGS.

SKU: 912510

Compare where it counts

In an in-vitro antimicrobial efficacy testing of the 0.5% PVP-I preservative in the BD Surgiphor™ Surgical Wound Irrigation System solution demonstrated a faster time to kill for Methicillin-resistant Staphylococcus aureus at all time points up to 5 minutes compared to diluted 0.05% Chlorhexidine Gluconate solution.*[1]

In an in vitro study, BD Surgiphor™ exhibited minimal toxicity when compared to dilute chlorhexidine irrigation solution and ethanol and benzalkonium chloride solution at 24 hours[1,3,4]

Demonstrated a greater bacterial reduction compared to saline irrigation when delivered with similar delivery methods*[1]

To order BD Surgiphor™ Surgical Wound Irrigation System, contact your BD sales rep.

Product description: BD Surgiphor™ Surgical Wound Irrigation System is a surgical wound irrigation medical device containing a ready-to-use sterile povidone-iodine (PVP-I) solution (Surgiphor™ Solution). Surgiphor™ Surgical Wound Irrigation System is primarily intended to mechanically loosen and rinse debris and foreign materials, including microorganisms from the surgical wound. The device consists of a screw cap and a sealed bottle containing 0.5% w/w PVP-I in a solution of phosphate-buffered saline, potassium iodide and Vitamin E TPGS. As an ancillary action, PVP-I serves as a preservative to protect the solution from microbial growth during use, whilst also reducing the bacterial load within the wound by killing the microorganisms that could lead to infection. Surgiphor™ Surgical Wound Irrigation System is intended to be used by healthcare practitioners, in a healthcare environment, in a general population of patients, excluding neonates, where surgical wound irrigation is appropriate. No specific training is required prior to using Surgiphor™ Surgical Wound Irrigation System. **Intended purpose:** Surgiphor™ Surgical Wound Irrigation System is intended to mechanically loosen and remove debris and foreign materials, including microorganisms from the surgical wound. **Contraindications:** Do not use Surgiphor™ Surgical Wound Irrigation System in patients with history of allergic reactions to Surgiphor™ Solution components. Do not combine Surgiphor™ Surgical Wound Irrigation System with antiseptic solutions, such as octenidine due to potential reactions. Do not use Surgiphor™ Surgical Wound Irrigation System in neonates (less than 28 days after birth). **Warnings:** Do not use or mix Surgiphor™ Solution with antimicrobial cleansers, soaps, lotions, or ointments. Do not use Surgiphor™ Surgical Wound Irrigation System if the packaging is damaged or if the seal integrity is compromised. Surgiphor™ Surgical Wound Irrigation System is for single use only. Reprocessing or re-sterilization may compromise the integrity of the device. Reuse on more than a single patient may create a risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Surgiphor™ Solution may cause allergic reactions such as anaphylactic shock, rash, or skin irritation in patients with iodine allergy. Discontinue use immediately if irritation or an allergic reaction occurs. Do not use Surgiphor™ Solution for injection or infusion. Do not swallow Surgiphor™ Solution. Do not use and avoid contact with eyes and ear canals due to potential visual and ear (ototoxicity) impairment. Do not use more than 24 hours after puncturing the bottle. **Precautions:** May cause a temporary irritation and/or burning sensation on exposed skin in very rare cases. Single use only. Do not use past the expiration date. Not for at-home use. There is no evidence of mutagenic or embryo toxicity associated with the ingredients of the product. Due to lack of relevant clinical trials and clinical experience with pregnant or with breast-feeding women, Surgiphor™ Surgical Wound Irrigation System should only be used after a Health Care Practitioner's medical benefit-risk assessment in these patients. **Residual risks and undesirable side effects:** Allergic reaction is a potential residual risk that may occur with the use of Surgiphor™ Surgical Wound Irrigation System. Please consult product insert for complete indications, contraindications, warnings, precautions, safety information and instructions for use.

***Surgical wound was in a simulated animal model.**

References: 1. BD data on file. Data generated in a preclinical model. Data may not correlate to performance in humans. **2.** (ATCC #33591) Product should be used only within 24 hours of opening per IFU. **3.** 5-10% dilution in MTT assay. **4.** Referenced products are not intended to remain in wound beyond indication.

STERILE SOLUTION™

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