Bactisure™ Wound Lavage

Advancing Biofilm Removal



Bactisure Wound Lavage is used to remove debris, including microorganisms, from wounds using pulsed (jet) lavage. The clear, colorless, low-odor solution is a FDA 510(K) cleared device. Active ingredients include ethanol (solvent), acetic acid (pH modifier), sodium acetate (buffer), benzalkonium chloride (surfactant), and water. Product is available in sterile 1000 mL polypropylene plastic bags with an integrated single spike port.



A New Approach to Biofilm Removal

Bacteria can produce Extracellular Polymeric Substance (EPS) to shield themselves from both mechanical and chemical attack. Bactisure Wound Lavage was specifically designed to remove these structurally resistant forms of bacteria. Our solution physically deconstructs the protective EPS matrix, making bacteria more susceptible to traditional antibiotics and the body's normal defense mechanisms.

Indicated for Use on All Wound Types

- Apply just prior to wound closure using Zimmer Biomet Pulsavac[®] Plus or similar pulsed lavage system.
- Immediately rinse with an equal amount of normal saline using pulsed lavage.
- Not intended for repeated use.
- Not indicated for use during dressing changes or for use by soaking the product into dressings.
- Do not use if there is a history of allergy to any of the ingredients.

Does Not Harm Human Tissue*

- Safe for use NAMSA Toxicology Report¹
- Non-irritant ISO Intramuscular Implantation Test with Histopathology²
- Normal wound healing Porcine Dermal Testing³

Deconstructs and Removes



Deconstructs

Bactisure Wound Lavage breaks up crosslinks within biofilm EPS.

With EPS crosslinks removed, Bactisure Wound Lavage solubilizes biofilms for easy removal via pulsed lavage. Exposed bacteria are subject to lavage removal or inactivation via traditional antibiotics and the body's normal defense mechanisms.

Biofilm's Role in Chronic Wound Infections

- Over 90% of all bacteria exist in biofilms.⁴
- Biofilms are formed in the body when bacteria coalesce on surface structures and produce an Extracellular Polymeric Substance (EPS).⁴
- The EPS then shields bacteria from both mechanical and chemical attack.⁴
- EPS shielded bacteria in a biofilm can be 1000x more resistant to antibiotics than planktonic (free-floating) bacteria.4
- The periodic release of planktonic bacteria from biofilms have been linked to chronic relapsing infections.⁵

Figure 1 – Mature Biofilm/EPS Removal: Static vs. Pulsed Lavage Performance⁷

2-Min. Static and 30-Sec. Pulsed Lavage, Tivanium Substrate







Figure 3 – Mature Biofilm/EPS Removal⁹

2-Min. Static - Stainless Steel Substrate



Enhancing Wound Care

Irrigation and debridement are considered essential components of wound management and infection control.⁶ Bactisure Wound Lavage can enhance these standard wound care practices when used as an adjunct to normal saline wound lavage⁷ (See Figure 1). Moreover, independent laboratory testing suggests that Bactisure Wound Lavage can effectively remove common wound pathogens including the bacteria found in biofilms^{8,9} (See Figures 2 and 3). Bactisure Wound Lavage also conforms to USP <51> requirements for rapid in-solution inactivation of common pathogens.^{10,11}



Ordering Information

Bactisure Product



Bactisure Wound Lavage – 1L Bag, 6/BX

00888700100

Bactisure Pulsavac Plus Kits*



Bactisure Component Kit with Dual Spike Y-Connector Bactisure Fan Spray Kit with Dual Spike Y-Connector Bactisure Hip Kit with Dual Spike Y-Connector Bactisure Shower Spray Kit with Dual Spike Y-Connector

00888742000 00888747500 00888748200 00888749500

Bactisure Pulsavac Plus A/C Kits*



Bactisure A/C Component Kit with Dual Spike Y-Connector	00888742600
Bactisure A/C Fan Spray Kit with Dual Spike Y-Connector	00888747600
Bactisure A/C Hip Kit with Dual Spike Y-Connector	00888748600
Bactisure A/C Shower Spray Kit with Dual Spike Y-Connector	00888749600

*Each kit includes 6 1L bags of Bactisure Wound Lavage and 6 Pulsavac handpieces with Dual Spike Y-Connectors

From diagnosis to treatment, Zimmer Biomet provides the most comprehensive portfolio for the continuum of care.



Therapy

Once infection has been diagnosed, defeating the organism is vital. In conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection), Zimmer Biomet's modular and monoblock spacer molds and lavage systems are designed to help meet these needs.



Synovasure

Re-Implantation

After the infection has been diagnosed and treated, Zimmer Biomet's specialized antibiotic loaded cements and your choice of implant to provide symptom relief and restore joint function. Zimmer Biomet offers a wide range of proven revision implant systems for re-implantation.

Diagnostics

Synovasure[®] Alpha Defensin is a unique, reliable and reproducible test designed and validated to aid in the diagnosis of Periprosthetic Joint Infection (PJI). It identifies elevated levels of Alpha Defensin, a critical protein in the innate immune response to infection.

References

- 1. North American Science Associates (NAMSA) Safety Evaluation Report, N142006, per ISO 10993-12 & 10993-18.
- 2. ISO Intracutaneous Reactivity Testing, WuXi AppTec protocol #9107015-5, per ISO 10993-10.
- 3. Porcine Dermal Full-Thickness Wound Wash Study, WuXi AppTec report 32255.
- Montana State University. (n.d.). Biofilm Basics: Section 1. Retrieved from http://www.erc.montana.edu/biofilm-basics/ what_are_biofilms.html.
- Costerton, J. W., Stewart, P. S., & Greenberg, E. P. (1999). Bacterial biofilms: a common cause of persistent infections. Science (New York, N.Y.), 284(5418), 1318-22.
- 6. Hannigan et al, Adv Wound Care 2015; Parvisi et al, Bone & Joint J 2013; Mak et al, Int J Nurs Stud 2015.
- 7. Dr. Garth James, Montana State University Center for Biofilm Education; Next Science report TR-02-14-025.
- 8. Antimicrobial Test Labs, Inc. study GLP1175.
- 9. Dr. Garth James, Montana State University Center for Biofilm Education; Next Science report TR-02-14-010.
- 10. Antimicrobial Test Labs, Inc. study GLP1177.
- Note: Reductions in microbial growth in solution have not been shown to definitively correlate with reductions in infections in patients.

Contact your Zimmer Biomet representative or visit us at www.zimmerbiomet.com/surgical



The Zimmer Biomet Clinical Excellence Team consists of Perioperative Nurses who provide product education, training and support for Bactisure Wound Lavage. For more information about the Clinical Excellence Team please contact SurgicalSales-ClinicalExcellence@zimmerbiomet.com.



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