The Untapped Opportunity

To Reduce Surgical Infections

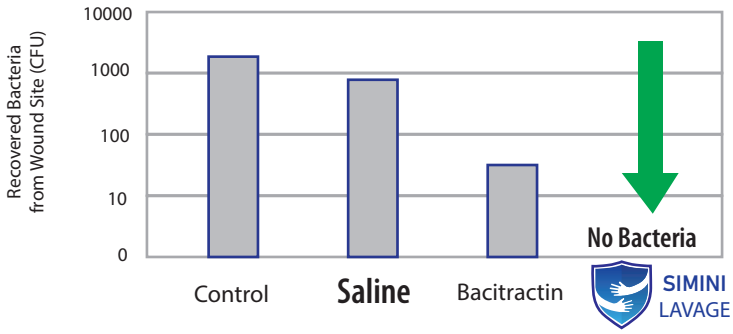
PRODUCT BENEFITS

IN SURGERY PROTECTION	Best Line of Defense for Infection
ENHANCE ASEPTIC TECHNIQUE	Reduced 99.98% of bioburden in a human clinical study
DISRUPT BIOFILMS	The key to exposing bacteria for effective removal
NON-ANTIBIOTIC PRODUCT	Can remove resistant bacteria including MRSP

Simini Protect Lavage

KEY DATA SUMMARY

Improvement over Saline



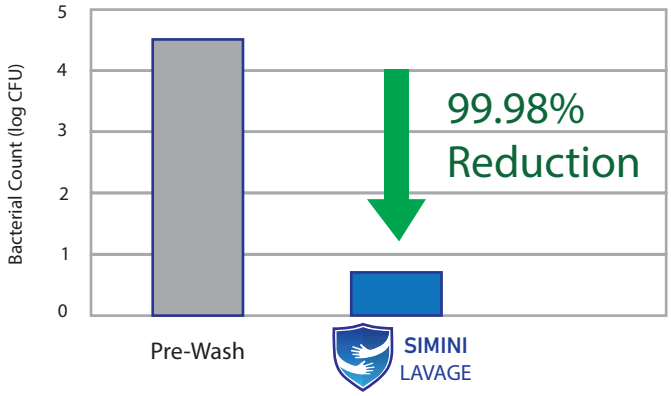
Murine Surgical Model

Staph. Aureus
Bacteria removal from surgical wound
(50 CFU inoculum, 40-60 minute growth)

Texas Tech University
Surgical Murine Model with Biofilm

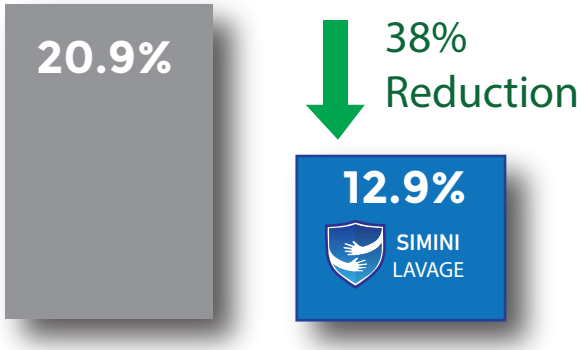
CLINICAL DATA

Reduced Bioburden



Culture Positive Pre-Wash

Reduced Infection



Historical Infection Rate

Simini Lavage Study
Infection Rate

Human Clinical Study

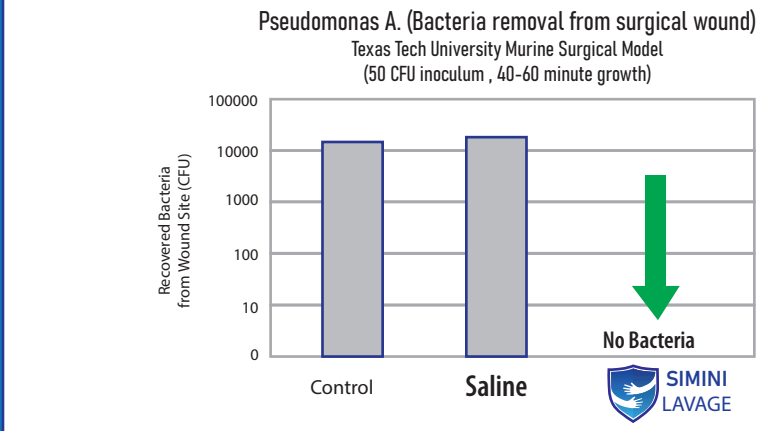
40 prosthetic joint infection patients (Total knee replacement)
(Infection rate 90-day post revision surgery)

Hunter et al., "Clinical Effectiveness of a Biofilm Disrupting Surgical Lavage in Reducing Bacterial Contamination in Total Knee Arthroplasty Revision Surgery in Known Cases of Prosthetic Joint Infection", Zimmer Biomet white paper. (administered 1 litre volume via pulsed jet lavage)
* Wu et al., "Arthrodesis Should be Strongly Considered After Failed Two-Stage Reimplantation TKA" Clin Orthop Relat Res (2014) 472:3295-3304

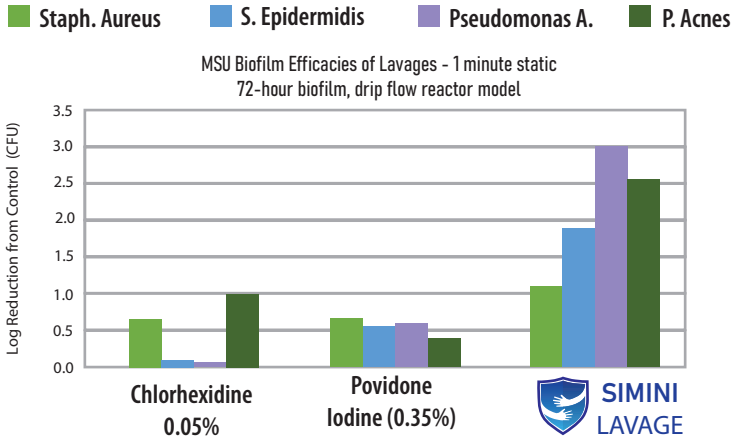
The Untapped Opportunities

Filling the Gaps in Infection Control

Removing bioburden from surgical wounds[1]



Antimicrobial therapy is futile against biofilm[1]



1. Verwilghen, D., Singh, A., "Fighting surgical site infections in small animals: are we getting anywhere?," Vet Clin North Am Small Anim Pract. 2015 Mar;45(2):243-76

Product Ingredients

- Ethanol
- Acetic Acid
- Sodium Acetate
- Benzalkonium Chloride (0.13%)
- Water

Safety Studies

ISO Intramuscular Implantation Test with Histopathology
(14 day rabbit study) - Simini Protect Lavage
- No abnormal clinical signs
- Lavage was considered a "Non-Irritant" as compared to predicate device

Dermal Testing - Uninfected wounds
(14 day porcine study) - Simini Protect Lavage
- Lavage resulted in normal wound healing and was comparable to a predicate device