

Never Compromise

Safety or Efficacy





Evolving Practice means Never Compromise

Wound bed preparation and cleansing technologies have significantly evolved in the last decade. Newer products now take into consideration the need for a cleanser that can disrupt microbial colonies while maintaining the integrity of key wound healing cells.

As a result, expert guidelines now include evidence-based recommendations that can lead to improved outcomes and cost savings without compromising safety and effectiveness.

Following evidence-based consensus guidelines

Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline

The International Guideline 2019

NPIAP

National Pressure Injury Advisory Panel

International Guidelines

November 2019



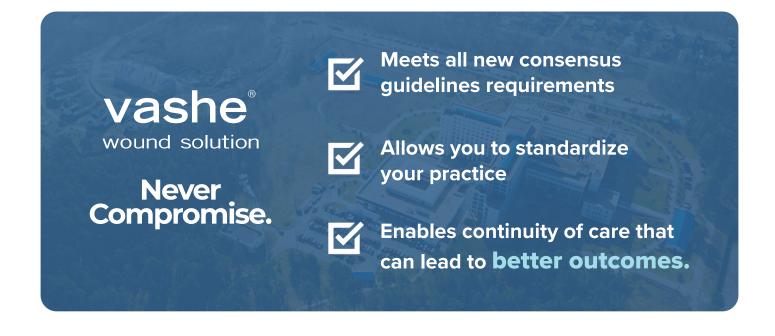




Limited evidence exists on the ability of saline to address high levels of microbes or bacteria present in chronic wounds, while other antimicrobial preservatives present in cleansers could compromise wound healing. Using a cleanser that can remove or disrupt microbial colonies is a critical component to wound healing.^{2,3}

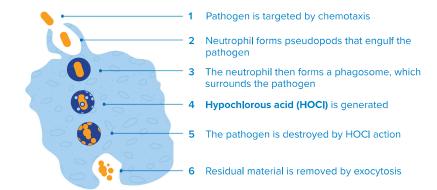
The ideal cleansing solution should balance the need for removal of microbial colonies while avoiding damage to key wound healing cells. Cytotoxicity to these key cells; fibroblasts, keratinocytes, vascular and endothelial cells should be considered as they are required to heal the wound.²⁻⁵

Traditional cleansers such as hydrogen peroxide, traditional sodium hypochlorite (e.g. Dakin's solution), povidone-iodine and chlorhexidine are proven to be cytotoxic to necessary healing cells, which leads to "hard-to-heal" wounds burdening healthcare. A wound cleanser for frequent use should both disrupt and remove germs/microbes and preserve wound cells to promote a healthy wound environment.²⁻⁵



Replicating the body's natural response to invading pathogens:

After a pathogen enters the body, neutrophils are quickly deployed from the bloodstream to respond. Through a complex biochemical pathway, Pure hypochlorous acid (pHA) is produced naturally by the human body to neutralize invading pathogens.



Proven efficacy 💥



A recent prevalence study confirmed that almost 80% of chronic wounds contain high levels of microbes.⁶⁷ Those microbes are thought to be the root cause of ~80% of all infections in humans and responsible for potentially delaying healing in 60% of chronic wounds.8,9



Pure hypochlorous acid (pHA) has the ability to disrupt microbial colonies after short exposure10



No known clinically relevant resistance to pHA, non-mutagenic properties unlike other solutions (antimicrobials and antibiotics)



80-100 times more effective than sodium hypochlorite^{11,12}



Effective as a preservative against fungi, spores, viruses and multi-drug resistant bacteria

When a pHA-preserved wound cleanser is used in clinical studies, significant quantities of pathogens are mechanically removed from wounds, allowing the immune system to sustain the reductions.¹³⁻¹⁵

| Organism | Time to kill | % Reduction |
|-------------------------|--------------|-------------|
| MRSA | 15 seconds | 99.999% |
| VRE | 15 seconds | 99.999% |
| Escherichia coli | 15 seconds | 99.999% |
| Acinetobacter baumannii | 15 seconds | 99.999% |
| Bacteroides fragilis | 15 seconds | 99.999% |
| Candida albicans | 15 seconds | 99.999% |
| Enterobacter aerogenes | 15 seconds | 99.999% |
| Enterococcus faecium | 15 seconds | 99.999% |
| Haemophilus influenzae | 15 seconds | 99.999% |
| Klebsiella oxytoca | 15 seconds | 99.999% |
| Klebsiella pneumoniae | 15 seconds | 99.999% |

| Organism | Time to kill | % Reduction |
|------------------------------|--------------|-------------|
| Micrococcus luteus | 15 seconds | 99.999% |
| Proteus mirabilis | 15 seconds | 99.999% |
| Pseudomonas aeruginosa | 15 seconds | 99.999% |
| Serratia marcescens | 15 seconds | 99.999% |
| Staphylococcus epidermidis | 15 seconds | 99.999% |
| Staphylococcus haemolyticus | 15 seconds | 99.999% |
| Staphylococcus hominis | 15 seconds | 99.999% |
| Staphylococcus saprophyticus | 15 seconds | 99.999% |
| Streptococcus pyogenes | 15 seconds | 99.999% |
| Staphylococcus aureus | 15 seconds | 99.995% |
| C. difficile endospores | 15 seconds | 99.93% |

Proven safety



Based on years of clinical experience, evidence and extensive testing, Vashe helps to accomplish the goals of wound bed preparation and has proven to be:



Non-irritating



Safe for key cells



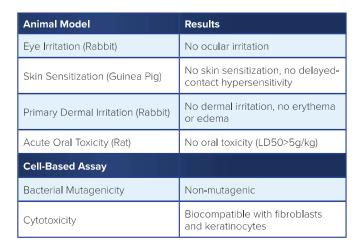
Safe around mucous membranes



Has no known contraindications



FDA cleared





| Wound Irrigant | Results | % Cell Survival (Fibroblasts & Keratinocytes) |
|---|---------|---|
| Hypochlorous Acid (@ $\underline{4x}$ the normal % of Vashe Wound Solution) | Pass | > 75% |
| Saline (0.9% NaCl, pH 5.0) | Pass | > 75% |
| Dakin's Solution (0.25%) | Fail | < 25% |
| Dakin's Solution (0.5%) | Fail | < 25% |
| Chlorhexidine gluconate (4%) | Fail | < 25% |
| Hydrogen peroxide (3%) | Fail | < 25% |
| Povidone iodine (7.5%) | Fail | < 25% |
| Povidone iodine (10%) | Fail | < 25% |

Hypochlorous acid (at four times the normal percent of Vashe) is non-cytotoxic (grade 0), in contrast to other commonly used cleansers with significant cytotoxic effects¹⁶

A study was conducted in an outpatient wound center where Vashe was used for general cleansing on 31 patients. This study found that:

- 86% of chronic wounds healed
- Pain was reduced from 4.7 visual analog scale (VAS) to 0 at the end of the evaluation
- Odor was reduced from 4.58 VAS to 0 at the end of the evaluation¹⁷



The importance of pH

Wound healing is optimal in slightly acidic environments where antimicrobial properties are higher. *Pure* hypochlorous acid has a pH between 3.5 and 5.5, which is favorable to wound healing environments that can aid in:¹⁸

- Optimal protease activity and oxygen release¹⁹
- Reduced toxicity of bacterial end products²⁰
- Epithelization and angiogenesis^{21,22}
- Increased macrophage and fibroblast activity^{21,23,24}

Many cleansing solutions contain toxic ingredients, such as sodium hypochlorite, and have a highly alkaline pH. An alkaline environment can allow pathogens to thrive and potentially impede the healing process.²⁵

Chlorine, Hypochlorous Acid, and Sodium Hypochlorite Abundance Based on pH + Relative pH of Wound Types and Various Solutions Used

