Vashe®



Debridement, Irrigation | Disrupts biofilm | Proven safety profile Fast, effective removal of bacteria, fungi, and spores SteadMed[®]



Features and Benefits

THE PERFECT COMBINATION OF SAFETY AND EFFICACY NEEDED FOR IDEAL IRRIGATION AND HEALING

Vashe® Wound Solution helps to cleanse the wound and accomplish the goals of wound bed preparation in a biocompatible, safe, effective and natural way. This solution of hypochlorous acid (HOCI), developed through a proprietary electrochemical process, has been thoroughly safety-tested. Hypochlorous acid acts as a preservative that inhibits microbial contamination within the solution. It is non-cytotoxic, non-irritating, and non-sensitizing. It has no clinical contraindications for use.

The Human Inflammatory Response



HARNESSING THE IMMUNE RESPONSE FOR TOPICAL TREATMENT OF SURGICAL, TRAUMATIC AND CHRONIC WOUNDS

Hypochlorous acid, the final product of the oxidative burst pathway inside the human white blood cell, kills invading pathogens as part of the natural human immune inflammatory response. Without appropriate blood flow, which is absent in many chronic wounds, there is a shortage of resources provided by white blood cells to begin defense and repair of the wound. With Vashe Wound Solution, hypochlorous acid can be harnessed to assist in wound activity and, ultimately, wound resolution.

Toxicological evaluation demonstrated that Vashe Wound Solution is non-irritating, non-sensitizing, non-mutagenic, and showed no oral toxicity.

Biocompatibility and Toxicity Data for Vashe Wound Therapy¹

Animal Model	Results
Eye Irritation (Rabbit)	No ocular irritation
Skin Sensitization (Guinea Pig)	No skin sensitization, no delayed-contact hypersensitivity
Primary Dermal Irritation (Rabbit)	No dermal irritation, no erythema or edema
Acute Oral Toxicity (Rat)	No oral toxicity (LD50>5g/kg)
Cell-based Assay	
Bacterial Mutagenicity	Non-mutagenic
Cytotoxicity	Biocompatible with fibroblasts and keratinocytes

Hypochlorous acid (at 4 times the normal % of Vashe Wound Solution) is non-cytotoxic (Grade 0) in contrast to other commonly used cleansers that had significant cytotoxic effects (Grade 3).

Comparative Cytotoxicity Testing of Hypochlorous Acid and Commonly Used Wound Irrigants Against Human Dermal Fibroblasts and Keratinocytes (n=5 per group, p<0.01)¹

Wound Irrigant	Results	Grade
Hypochlorous Acid (@ 4 times the normal % of Vashe Wound Therapy)	Pass	0
Saline (0.9% NaCl, pH 5,0)	Pass	0
Dakin's Solution (0.25%)	Fail	3
Dakin's Solution (0.5%)	Fail	3
Chlorhexidine gluconate (4%)	Fail	3
Hydrogen peroxide (3%)	Fail	3
Povidone iodine (7.5%)	Fail	3
Povidone iodine (10%)	Fail	3

Proven Effectiveness

Organism	Time to kill	% Reduction	Organism	Time to kill	% Reduction
MRSA	15 seconds	99.999%	Micrococcus luteus	15 seconds	99.999%
VRE	15 seconds	99.999%	Proteus mirabilis	15 seconds	99.999%
Escherichia coli	15 seconds	99.999%	Pseudomonas aeruginosa	15 seconds	99.999%
Acinetobacter baumannii	15 seconds	99.999%	Serratia marcescens	15 seconds	99.999%
Bacteroides fragilis	15 seconds	99.999%	Staphylococcus epidermidis	15 seconds	99.999%
Candida albicans	15 seconds	99.999%	Staphylococcus haemolyticus	15 seconds	99.999%
Enterobacter aerogenes	15 seconds	99.999%	Staphylococcus hominis	15 seconds	99.999%
Enterococcus faecium	15 seconds	99.999%	Staphylococcus saprophyticus	15 seconds	99.999%
Haemophilus influenzae	15 seconds	99.999%	Streptococcus pyogenes	15 seconds	99.999%
Klebsiella oxytoca	15 seconds	99.999%	Staphylococcus aureus	15 seconds	99.995%
Klebsiella pneumoniae	15 seconds	99.999%	C. difficile endospores	15 seconds	99.93%

Vashe Wound Solution has been tested against many common pathogens, including fungi, spores, and multi-drugresistance bacterial strains. In clinical studies, the organisms are removed from the wounds in great numbers allowing the immune system to sustain the reductions.²⁻⁴

MINIMAL CHANCE OF RESISTANCE TO HOCI COMES DOWN TO MECHANISMS OF ACTION

Antibiotic resistance is of increasing concern to clinicians and hospital administrators alike. Antibiotics and antimicrobials such as silver and chlorhexidine gluconate – recognized as relative gold standards in certain applications and practices – have documented resistance to various strains of bacteria.⁵⁻⁷ There has been no resistance reported to hypochlorous acid. This molecule is native to the human and is reported to have several possible mechanisms of antimicrobial action to kill bacteria *in vitro*. These may be responsible for the lack of documented resistance to hypochlorous acid.

McKenna and Davies reviewed the inhibition of bacterial growth by hypochlorous acid.⁸ They concluded that even low concentrations of hypochlorous acid exert a rapid and selective inhibition of bacterial cell growth and cell division. In brief, they also observed that hypochlorous acid can oxidize nucleotides, inactive enzymes and the electron transport system, disrupt cell membranes, and fragment proteins. Their work, and that of others, describes a molecule that can apparently impact several critical bacterial cell functions.



The Importance of pH for Progress

The activity of chlorine-based solutions is dependent upon pH. Lowering the pH into a range of 4-6 results in hypochlorous acid as the dominant species and a pH that mimics that of intact human skin. As a result, the activity increases by a factor of 80-100 times that observed in higher-pH solutions such as Dakins, while the lower pH apparently eliminates cytotoxicity and confers sporicidal activity.⁹¹⁰ Additional research has confirmed sodium hypochlorite to be cytotoxic at concentrations of 0.0005%, inducing unnecessary harm to fibroblasts and related cells participating in the healing processes.¹¹

With this in mind, Vashe Wound Solution, a hypochlorous acid solution, is formulated at a pH range of 5.0-5.5. Data derived from our studies have documented its skin-friendly nature and the absence of cytotoxicity.





The pH of Vashe Wound Solution plays a vital role in the healing environment. In fact, not only does it have an impact on the antimicrobial efficacy of chlorine in solution, it also has a positive impact on the pathophysiology associated with positive cell activity in wounds. Particularly, a review by Nagoba, et al., noted that an acidic environment played a role in the:

- Alteration of protease activity¹²
- Release of oxygen^{13,14}
- Reduction of toxicity and bacterial end products¹⁵
- Supports epithelialization and angiogenesis^{14,16}
- Destruction of abnormal collagen, increase in macrophage and fibroblast activity, controlling activity of various enzymes participating in wound healing^{14,17,18}

Vashe Indications and Recommended Use

Vashe Wound Solution is intended for cleansing, irrigating, moistening, debriding, and removing foreign material, including microorganisms, from:

- Acute and chronic dermal lesions
- Stage I-IV pressure ulcers
- Stasis ulcers
- Diabetic ulcers
- Post-surgical wounds
- First- and second-degree burns
- Abrasions and minor irritations of the skin
- Grafted and donor sites

It can be applied in the following applications:



Packing dressing



General wound cleansing



Negative pressure wound therapy with instillation and dwell (NPWT-id)



Pulse lavage



Bulb syringe



Adjunctive debridement modalities

Protocol for Use in Chronic Wounds

PROVEN SAFE AND EFFECTIVE FOR ADVANCING THE PROGRESS OF NON-HEALING WOUNDS

- Irrigate the wound and peri-wound area with Vashe Wound Solution to remove cellular debris and excessive wound drainage from the area to be treated.
- Refresh the treated area with additional Vashe Wound Solution, allowing it to pool in wound areas that have sufficient depth.
- Saturate the wound dressing with Vashe Wound Solution, then apply the dressing for:
 - <1 minute: wounds without biofilm
 - 3-5 minutes: wounds with biofilm, slough, and/or necrosis
 - 10 minutes or as a dressing: heavy amounts of non-viable tissue

Results

GENERAL WOUND CLEANSING

Vashe was used for general wound cleansing with 31 patients in an outpatient wound care center. This study found:

- 86% of chronic wounds healed at evaluation end
- Dramatic reduction in pain
 - Average 4.7 visual analog scale (VAS) score upon enrollment, reduced to zero at evaluation end
- Wound odor completely eliminated
 - Average 4.58 VAS score upon enrollment, reduced to zero at evaluation end¹⁹

Percentage of Wounds Healed



ADJUNCTIVE DEBRIDEMENT

Vashe can be used with other debriding techniques such as enzymatic debriding agents. In a study by Miller and Mouhlas, significant cost savings were achieved by using Vashe on a wound prior to application of Santyl® enzymatic debriding agent.²⁰ In addition to removing foreign bodies and bacteria, Vashe has been shown to disrupt biofilm in the wound, an impediment to optimal wound bed preparation.

Vashe has been successfully used with enzymatic debriding agents in a long-term care setting to assist with wound bed preparation in patients enduring chronic wounds with slough and necrosis.²⁰ A control group paired the enzymatic debriding agent with saline, while the experimental group used Vashe prior to the enzymatic debriding agent.

	Control nortical	Trial maria d
	Control period	Inal period
Patients (N)	26	36
Wounds (N)	51	43
Expenditure for enzyme	\$39,544.16	\$14,410.16
Expenditure for Vashe	na	\$878.40
Cost Santyl per patient	\$1,521	\$400
Cost Santyl per wound	\$775	\$335
Cost Vashe per patient	na	\$24
Cost Vashe per wound	na	\$20
Total debridement cost per patient	\$1,521	\$424
Total debridement cost per wound	\$775	\$355

Use with Negative Pressure Wound Therapy: MINIMIZE RISK THROUGH BIOFILM DISRUPTION AND REMOVAL OF CAUSATIVE PATHOGENS

Negative Wound Pressure Therapy is one of the most documented wound therapies in the world.²¹ Recently, the instillation application was added to the portfolio of these products. Vashe is effective at disrupting biofilms and removing debris and microorganisms from wounds, resulting in faster healing, fewer OR visits, and earlier discharges when compared to saline and Dakin's solution.^{22,23}

Solution Used	Mean Operating Room Visits	Length of Stay	Days to Closure
NaOCI/NaCI	7	25	37
Vashe	3.2	14	30

Use in the Presence of Biofilm:

Additional studies have suggested the use of Vashe as an instillation solution with Negative Pressure Wound Therapy led to faster granulation tissue formation and healthier wound beds.²⁴

Biofilm, the exopolymeric substance secreted by and surrounding bacteria, has presented many problems in the healing of wounds. Estimates suggest biofilm is present and potentially delaying healing in 60% of chronic wounds.²⁵ Vashe has been studied extensively in its ability to disrupt biofilms. Laboratory studies have shown that hypochlorous acid has the ability to disrupt 90% of biofilms after just a short order of exposure.²² Disrupting biofilm is a crucial element of any wound care clinician's armamentarium in treating chronic wounds.

Effect of Hypochlorous Acid on Biofilm S. aureus Bacterial Numbers



Effect of Hypochlorous Acid on Polysaccharide Levels Within *S. aureus* Biofilm Matrix



Effect of Hypochlorous Acid on Protein Levels within *S. aureus* Biofilm Matrix



Use of Vashe in Irrigation: LEAVE NOTHING TO CHANCE — GET BACTERIAL COUNTS DOWN AND KEEP THEM DOWN

Vashe Wound Solution has demonstrated superior outcomes related to flap closure when compared to saline. This study used ultrasonic debridement systems 7 days prior to closure, and bacteria counts were measured through quantitative bacteriology. In wounds treated with Vashe, bacteria counts not only diminished, but stayed low for up to 7 days, resulting in 50% greater closure than saline treated wounds.²⁶

Ultrasonic Debridement Solution	Initial Bacteria Count	Post- Debridement Count	7 days Post-Debridement Count	Failure Rate of Flap
NaCI .9%	>106	10 ²	>105	80%
Vashe	>106	10 ²	10 ²	25%

BURNS AND THE USE OF VASHE

Many solutions used in burn centers have great killing power; however, they also have a high degree of cytotoxicity. Vashe has the right balance of bacteria removal and avoidance of cytotoxicity necessary for the thermally injured patient. Vashe demonstrated incredible value in its ability to assist with graft take in burn patients, while reducing costs.²⁷ Additionally, Vashe is proven to be a successful component in universal decontamination protocols as the solution for bathing rituals to help assist in bacteria removal in burn patients, contributing to great success in MRSA rate reduction.²⁸

Burn indications for the use of Vashe:

- Irrigation
- Moistening Skin Grafts
 Cleansing
- Debridement
- Bed Bathing

Vashe Product Information

Bottle Size/Pack Size	Vashe Wound Solution	Vashe Wound Solution for Instillation Applications*	4
4.0 fl. oz. (118-ml) Bottles/24-Pack	00312	Not available	<u> </u>
8.5 fl. oz. (250-ml) Bottles/12-Pack	00313	00316]
16.0 fl. oz. (475-ml) Bottles/12-Pack	00314	00317	
34.0 fl. oz. (1 liter) Bottles/6-Pack	00322	00323	_
34.0 fl. oz. (1 liter) Bottles/6-Pack	00322	00323	

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