ADVANCED WOUND CLEANSING TECHNOLOGY

vashe®

Skin - Wound - Burn Cleansing Solution
- Debridement Irrigation
- Physical Disruption of Biofilm
- Removal of Microorganisms

16 fl. oz. (475 ml)

SteadMed®
Helping clinicians help patients.
**Vashe® Wound Solution** helps to cleanse the wound and accomplish the goals of wound bed preparation in a biocompatible, safe, effective, natural way. This solution of hypochlorous acid (HOCl), developed through a proprietary electrochemical process, has been rigorously 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 oral toxicity.
- It has no clinical contraindications for use.

**Safe for All Types of Wounds**

Unlike some wound irrigants that may inhibit wound healing, Vashe Wound Solution is produced at a skin-friendly pH, so it remains safe to patients, clinicians, and the environment.

The proprietary formulation of Vashe Wound Solution contains the highest concentration of hypochlorous acid.

**Comparative Cytotoxic Analysis**<sup>1</sup>

<table>
<thead>
<tr>
<th>Wound Irritant</th>
<th>Results</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vashe (HOCl)</td>
<td>Pass</td>
<td>0</td>
</tr>
<tr>
<td>Saline (0.9% NaCl, pH 5.0)</td>
<td>Pass</td>
<td>0</td>
</tr>
<tr>
<td>Dakin's Solution (0.25%)</td>
<td>Fail</td>
<td>3</td>
</tr>
<tr>
<td>Dakin's Solution (0.5%)</td>
<td>Fail</td>
<td>3</td>
</tr>
<tr>
<td>Chlorhexidine gluconate (4%)</td>
<td>Fail</td>
<td>3</td>
</tr>
<tr>
<td>Hydrogen peroxide (3%)</td>
<td>Fail</td>
<td>3</td>
</tr>
<tr>
<td>Povidone Iodine (7.5%)</td>
<td>Fail</td>
<td>3</td>
</tr>
<tr>
<td>Povidone Iodine (10%)</td>
<td>Fail</td>
<td>3</td>
</tr>
</tbody>
</table>

Comparative cytotoxicity testing of commonly used wound irrigants against human dermal fibroblasts and keratinocytes (n=5 per group, p<0.01)<sup>1</sup>

**Vashe Wound Solution meets the preservative effectiveness standards for *in vitro* kill times**<sup>2</sup>

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Initial Microorganism Count/ML</th>
<th>Microbe Kill Rate/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacteria</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td>Methicillin Resistant Staphylococcus aureus (MRSA)</td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td>Vancomycin Resistant Enterococcus faecalis (VRE)</td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td>Acinetobacter baumannii</td>
<td>$10^7$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td><em>Serratia marcescens</em></td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
<tr>
<td><strong>Fungi</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Candida albicans</em></td>
<td>$10^8$</td>
<td>100% at 15 sec.</td>
</tr>
</tbody>
</table>

**Vashe Indication**

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
- Exit sites

In addition, Vashe Wound Solution is used to moisten and lubricate absorbent wound dressings such as Drawtex® Hydroconductive Wound Dressing.

**Vashe Wound Solution**

**Safe:**
- Non-cytotoxic
- pH neutral to skin

**Effective:**
- Cleanses
- Debrides
- Removes microorganisms
Protocol for Use

- 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 to the wound bed for 3-5 minutes to support the removal of nonviable tissue.

If the application of a pre-soaked dressing is not practical due to the wound type or location:
- Pour directly onto the wound site to flush or flood the wound for the appropriate contact time.
- Use in various types of baths to soak the wound for the appropriate contact time.

Cleansing Contact Time

- Normal use: 3-5 minutes per application.
- For heavy amounts of necrotic tissue and slough: 5-10 minutes using a generous amount of Vashe Wound Solution and gauze dressing materials to irrigate and soak the wound prior to any debridement procedures.

Vashe Wound Solution Used as an Adjunct to a Standard Wound Care Protocol (n=31)

Wound Healing Results

- 86% of chronic wounds healed at evaluation end

**Percentage of Wounds Healed**

<table>
<thead>
<tr>
<th>Situation</th>
<th>Healed</th>
<th>Not Healed</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>60 days</td>
<td>55</td>
<td>45</td>
</tr>
<tr>
<td>90 days</td>
<td>79</td>
<td>21</td>
</tr>
<tr>
<td>End of study</td>
<td>96</td>
<td>14</td>
</tr>
</tbody>
</table>

- 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 end

Clinical Case Study

Diabetic Foot Amputation

Situation:

- Diabetic partial foot amputation
- Initial Treatment:
  - Negative Pressure Wound Therapy (NPWT)
  - Intravenous antibiotics
  - Hyperbaric oxygen therapy
- After NPWT, patient transitioned to cleansing with Vashe Wound Solution as part of the overall plan of care

Before cleansing with Vashe Wound Solution

After 6 Weeks of cleansing with Vashe Wound Solution
Vashe Wound Solution

- Biocompatible, safe, effective, natural
- Mimics the normal pH of human skin
- Cleanses, debrides and removes microorganisms from the wound
- Reduces wound odor
- Cleared for use on acute and chronic lesions
- Helps to accomplish the goals of wound bed preparation
- Non-cytotoxic, non-irritating, non-sensitizing, no oral toxicity
- No clinical contraindications for use
- Moistens and lubricates absorbent wound dressings, such as Drawtex Hydroconductive Wound Dressing
- Proprietary formulation

Vashe Wound Solution is available for purchase in the following packaging options, so you can choose the product and bottle size that best fits your practice. For prescription use only.

## Vashe Product Information

<table>
<thead>
<tr>
<th>Bottle Size/Pack Size</th>
<th>Vashe Wound Solution</th>
<th>Vashe Wound Solution for Instillation Applications*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0 fl. oz. (59-ml) Bottles/24-Pack</td>
<td>00324</td>
<td>Not available</td>
</tr>
<tr>
<td>4.0 fl. oz. (118-ml) Bottles/24-Pack</td>
<td>00312</td>
<td>00315</td>
</tr>
<tr>
<td>8.5 fl. oz. (250-ml) Bottles/12-Pack</td>
<td>00313</td>
<td>00316</td>
</tr>
<tr>
<td>16.0 fl. oz. (475-ml) Bottles/12-Pack</td>
<td>00314</td>
<td>00317</td>
</tr>
<tr>
<td>34.0 fl. oz. (1 liter) Bottles/6-Pack</td>
<td>00322</td>
<td>00323</td>
</tr>
</tbody>
</table>

*Must be used with a vented spike adapter set.

References:
2. Vashe Wound Solution data developed from USP 51 Antimicrobial testing.