Prontosan®

WOUND BED PREPARATION. TAKEN SERIOUSLY
The Problem - Biofilm

**THE PROBLEM**

Traditional wound cleansing with saline and water is ineffective at removing coatings and debris in many wounds, especially complex biofilms.

**FACT:** Over 90% of chronic wounds have a biofilm present which is a major barrier to wound healing.

**WHAT IS A BIOFILM?**

Biofilm forms when bacteria adhere to surfaces by excreting a thick, slimy, glue-like substance known as the Extracellular Polymeric Substance (EPS).

This substance forms a protective layer, where the bacteria are no longer free to move (planktonic), but adhere to the wound bed. New bacteria are produced and the colony grows under the protection of the EPS. Biofilms are often difficult to detect visually but delay wound healing due to the protection they provide to the bacteria in the wound bed.

**OVER 90% OF WOUNDS HAVE A BIOFILM**

**HOW DO BIOFILMS DEVELOP?**

- **CONTAMINATION**
  Free floating bacteria attach to a surface within minutes. Initial attachment is reversible.

- **SPREADING LEADS TO SYSTEMIC INFECTIONS**
  Mature biofilm releases bacteria within 2 – 4 days causing recolonisation, which results in a never ending biofilm cycle.

- **BIOFILM CYCLE**

- **COLONISATION**
  Bacteria multiply and become firmly attached within 2 – 4 hours.

- **BIOFILM DEVELOPMENT AND INFLAMMATORY HOST RESPONSE**
  Develop initial EPS and become increasingly tolerant to within 6 – 12 hours.
The Solution - Prevention and Management
Principles of Biofilm

THE SOLUTION
The prevention and management of biofilm in chronic wounds is rapidly becoming a primary objective of wound care, with the presence of biofilm acknowledged as a leading cause of delayed wound healing³.

Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel / Wound Gel X are one of few products specifically indicated for the prevention and removal of biofilms. Prontosan® contains two key ingredients: Betaine and Polyhexanide.

BETAINEx
A gentle effective surfactant (detergent) which is able to penetrate, disturb, clean and remove biofilm and wound debris.

BETAINEx MOLECULE

REDUCES SURFACE TENSION
Supporting softening, loosening and detaching of dirt, debris and biofilm

REMOVES AND HOLDS IN SOLUTION
Holds dirt, debris and biofilm in the solution, preventing recontamination.

POLYHEXANIDE (PHMB)
Promotes Healing, Minimises Bioburden

Polyhexanide is a highly effective broad spectrum antimicrobial that is active against gram negative and gram positive bacteria and yeast, including MRSA, Pseudomonas aeruginosa, VRE etc¹⁰. Polyhexanide has been in general use for about 60 years, it has demonstrated good clinical safety data (see overview page 5) with no evidence of resistance and minimal toxicity¹³, ¹⁴, ¹⁵. Polyhexanide has low to no absorption by human cells and tissue, therefore interference with the metabolism of the body is minimal.

Biofilm present
Mechanical rinsing with Wound Irrigation Solution
Betaine disrupts biofilm (removes dirt and debris)
Polyhexanide as adjuvant antimicrobial
Wound is cleansed, de-sloughed, debrided, decontaminated and free from biofilm
Prontosan® Breaks the Biofilm Cycle

A proactive approach using a combination strategy of Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel / Wound Gel X as part of wound bed preparation aims to:

- Reduce the biofilm burden (Prontosan® Wound Irrigation Solution)
- Prevent reconstitution of the biofilm (Prontosan® Wound Gel / Wound Gel X*)

Appropriate Time for Appropriate Wound

<table>
<thead>
<tr>
<th>CHRONIC WOUND - EPITHELIALISING</th>
<th>Rinse - soak - rinse with Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No slough</td>
<td>Cleanses the wound</td>
</tr>
<tr>
<td>Low exudate</td>
<td>Prevents biofilm</td>
</tr>
<tr>
<td>Highly fragile epithel tissue</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CHRONIC WOUND - GRANULATING</th>
<th>Rinse - soak - rinse with Solution</th>
<th>Apply Gel / Gel X*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light slough</td>
<td>Mechanically removes debris and slough (ideally use the Prontosan® Debridement Pad)</td>
<td></td>
</tr>
<tr>
<td>Low/medium exudate</td>
<td>Promotes wound healing</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CHRONIC WOUND - EXUDING/Colonised/Infected</th>
<th>Rinse - soak - rinse with Solution</th>
<th>Apply Gel / Gel X*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slough</td>
<td>Mechanically removes debris and slough (ideally use the Prontosan® Debridement Pad)</td>
<td></td>
</tr>
<tr>
<td>Medium/high exudate</td>
<td>Promotes wound healing</td>
<td></td>
</tr>
<tr>
<td>Stalled wound</td>
<td>Reduction of odor</td>
<td></td>
</tr>
</tbody>
</table>

* Apply Prontosan® Gel in wounds with cavities, Prontosan® Wound Gel X on larger surface wounds

Compatible with most common wound dressings.
Once opened, Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel / Wound Gel X can be used for up to 8 weeks (single patient use).
The results of this RCT with 289 subjects confirms the superiority of Prontosan® Wound Irrigation Solution compared to Saline in efficacy as it promotes the wound bed preparation, supports the reduction of inflammatory signs and accelerates the healing of vascular leg ulcers as well as pressure ulcers.

Both groups were comparable at the start of the study and the results obtained in the final assessment of lesions were as follows: Reversal of positive cultures (p=0.004), improvement in the healing process (p=0.000), reduction in lesion surface area (p=0.013); improvement in granulated tissue % (p=0.001), reduction in the % of slough in wound beds (p=0.002), reduction of the presence of exudate (p=0.008), reduction of the presence of purulent exudate (p=0.005), improvement in the condition of surrounding skin (p=0.021), reduction in pain (p=0.049), reduction in erythema in surrounding skin (p=0.004), reduction in surrounding skin edema (p=0.000), reduction in surrounding skin warmth (p=0.004) and reduction in odor (p=0.029).

If current thinking, that all chronic wounds are biofilm wounds (Woclick and Rhoads, 2008), is sustained then we will need to rethink our approach to wound cleansing, as the studies examined above indicate that PHMB, in conjunction with a surfactant, is superior to isotonic solutions. In addition, there is evidence emerging that Prontosan is an effective wound cleanser in longstanding (chronic) wounds and has been found by patients to be pain-free, improve patient quality of life, effectively manage wound infection and to reduce the overall time to healing.

PHMB appears to meet the criteria for an ideal antimicrobial agent, as described by Drossos et al (2003), and is available in presentations that provide clinicians with effective woundcare modalities for most clinical scenarios. Clinical use, both in the UK and the wider healthcare community, has shown PHMB-based wound-care products to be effective options for managing wound colonisation and infection and, so, deserve closer scrutiny.

Sufficient MRSA eradication could be shown in vivo on patients for the non-cytotoxic Polyhexanide […] In this article we discuss current therapeutic standards and potential alternatives for eradication of MRSA. There is evident need for effective, novel approaches for elimination of MRSA from chronic wounds that avoid the development of bacterial resistance; otherwise therapeutic alternatives for antibacterial treatment of chronic wounds will become limited.

The results of this observational study showed that the treatment of skin wounds of various kinds and types, in different ages, from pediatric age, until the geriatric age, with a polyhexanide and propyl betaine-based gel in combination with a secondary dressing showed significant improvements in the size of the wound, pain at dressing change, and wound characteristics.

Saline solutions were less efficient than a betaine surfactant containing wound rinsing solution in removing protein from adherent test wound coatings. Salt ions hinder the hydration of proteins and decrease protein solubility. Prontosan® Wound Irrigation Solution solubilized denatured proteins and aggregated by inclusion in betaine surfactant micelles. This is an essential property for thorough and gentle wound cleansing. Wound progress of leg ulcers was more positive when the wound was treated with Prontosan® Wound Irrigation Solution compared with saline solution. The wound antibacterial Octenisept did not seem suitable for wound cleansing because proteins were denatured and became insoluble.

The results of the RCT with 40 subjects show that the pH value of the wound was significantly (p<0.05) lower and that pain control was achieved (p<0.05) in the Prontosan treatment group compared to the Saline group. Saline group which was the control.

The results of the RCT with 40 subjects show that the pH value of the wound was significantly (p<0.05) lower and that pain control was achieved (p<0.05) in the Prontosan treatment group compared to the Saline group. Saline group which was the control.

For full evidence documents and other studies please visit www.bbraun.com
Wound Bed preparation. Taken Seriously

The clinical evidence demonstrates that by routinely introducing a Prontosan® regime as part of your patient pathway you will achieve better result.

- Improved patient outcomes, including time to heal\(^7\)
- Helps to prevent complications\(^{12}\)
- Helps to reduce spend on antimicrobials and antibiotics\(^{11}\)

How Prontosan® Saves You Money

In a model calculation for the UK\(^{11}\), based on the average reduction in treatment time of patients with Venous Leg Ulcers, the cost saving from changing to the Prontosan regime compared to saline is, on average, £400 per patient\(^8\).

<table>
<thead>
<tr>
<th>Breakdown of wound care costs(^5)</th>
<th>Cost drivers</th>
<th>How Prontosan® reduces costs</th>
</tr>
</thead>
</table>
| 40% Inpatient costs              | - Increased number of bed days  
- Complication rates             | - Infection rates reduced from 40% to 3%\(^6\)  
- Inflammatory signs reduced. BWAT Score p=0.0043\(^7\)  
- Decrease in incidence of reduction in bacterial counts\(^9\) |
| 40% Nursing time                 | - Length of treatment time     | - Treatment time reduced from 17 to 13 weeks\(^8\)  
- Wound size reduction. BWAT Score p=0.049. Granulation tissue improvement. BWAT Score p=0.043\(^7\) |
| 20% Dressing                     | - Cost of dressings            | - Dressing changes\(^6\)  
- Frequency of dressing changes  | - Silver dressings\(^6\) |

Helping compliance

At B. Braun we recognise the benefits of implementing a standardised approach to providing a better level of care and outcome. When implementing a Prontosan® pathway we will support you by providing educational packages to ensure compliance and to support your required educational needs.
The use of Prontosan® Wound Irrigation Solution and Wound Gel X contributed to the *speedy healing* of these diabetic wounds by reducing bioburden. Their use enabled the *painless* removal of sloughy tissue within one week. The patient spoke of *increased confidence* that his wounds would heal, directly as a consequence of using Prontosan®.


The patients quality of life improved with a *reduction in pain and a reduction in exudates levels* requiring only weekly dressings. Her mobility increased and she could begin to walk short distances again, allowing her to go out and *resume normal social activities*. The cost of wound management was reduced with only weekly visits by district nurses being required, compared to daily visits prior to intervention, and through reduced use of antibiotics.

Dowen, L. “Removal Of Biofilm In Infected Venous Leg Ulcers Using Prontosan® Wound Irrigation Solution And Gel”. European Wound Management Association (2010)

Historically, daily visits from the district nursing staff commenced in January 2001 and took one hour per day. Both the patient and his family found the visits a necessity but they felt that their lives revolved around treating the ulcers. Since commencing Prontosan®, visits from the district nurse were reduced to alternate days and the patient and his wife attended their son’s wedding, with no detrimental effect to either ulcer. This was the first time the patient had left his house to attend a social occasion for over 5 years. It has made significant improvements to both wounds which the patient, his wife and district nursing service did not expect to see. This has *improved the patient’s morale* and the results have motivated all nursing staff.


For full case study documents please visit: www.prontosan.co.uk
# Prontosan® Wound Irrigation Solution and Wound Gel / Wound Gel X

## Ordering Information

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Size</th>
<th>Pack Size</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prontosan® Wound Irrigation Solution</td>
<td>40 ml ampoule</td>
<td>24</td>
<td>400484</td>
</tr>
<tr>
<td></td>
<td>350 ml bottle</td>
<td>10</td>
<td>400403</td>
</tr>
<tr>
<td></td>
<td>1000 ml bottle</td>
<td>10</td>
<td>400446</td>
</tr>
<tr>
<td>Prontosan® Wound Gel</td>
<td>30 ml pod</td>
<td>20</td>
<td>400505</td>
</tr>
<tr>
<td>Prontosan® Wound Gel X</td>
<td>50 g tube</td>
<td>20</td>
<td>400517</td>
</tr>
<tr>
<td></td>
<td>250 g tube</td>
<td>20</td>
<td>400508</td>
</tr>
</tbody>
</table>

---

**REFERENCES:**

10. Kehn, K Polyhexanide: A Safe and Highly Effective Bicido, Skin Pharmacol Physiol 2010;23(suppl1):7-16
11. Data on file