Prontosan® Wound Irrigation Solution and Gel

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.¹

**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.²

**OVER 90% OF WOUNDS HAVE A BIOFILM¹**

**HOW DO BIOFILMS DEVELOP?²**

**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**

**COOLONISATION**
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.

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¹ Applicable only to Prontosan products sold in Canada

² Used with permission from Innovadyne, Inc.
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 healing. Prontosan® Solution and Prontosan® Gel are one of few products specifically indicated for the prevention and removal of biofilms. Prontosan contains two key ingredients: Betaine and Polyhexanide.

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

BETAINES 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 etc. Prontosan has a PHMB concentration of only 0.1% and is primarily used as a preservative, allowing to continue using the same bottle for up to 8 weeks after initial opening. Polyhexanide has been in general use for about 60 years, it has demonstrated good clinical safety data (see overview page 5).

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A proactive approach using a combination strategy of Prontosan® Solution and Prontosan® Gel as part of wound bed preparation may prove helpful and aims to:

- Reduce the biofilm burden (Prontosan Solution)
- Prevent reconstitution of the biofilm (Prontosan Gel)

**Appropriate Time for Appropriate Wound**

<table>
<thead>
<tr>
<th>DESCRIPTION OF WOUND</th>
<th>OBJECTIVE</th>
<th>HOW TO USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACUTE WOUND – SURGICAL PRIMARY &amp; SECONDARY INTENTION HEALING</td>
<td></td>
<td>Rinse with Solution</td>
</tr>
<tr>
<td>■ High risk patient*</td>
<td>■ Cleans</td>
<td>■ Soaks</td>
</tr>
<tr>
<td>■ No slough</td>
<td>■ Prevents biofilm/complications</td>
<td>■ Wounds</td>
</tr>
<tr>
<td>■ Minimal exudate</td>
<td></td>
<td>24/7 Action</td>
</tr>
</tbody>
</table>

| ACUTE WOUND e.g. trauma |            | Soak with Solution |
| Debris                  | ■ Cleans   | ■ Soaks       |
| Haematoma               | ■ Prevents biofilm/complications | ■ Wounds |

| CHRONIC WOUND – GRANULATING |            | Soak with Solution | Consider Gel |
| High risk patient*         | ■ Cleans   | ■ Soaks          |
| Low exudate                | ■ Prevents biofilm/complications | ■ Wounds |

| CHRONIC WOUND              |            | Soak with Solution | Apply Gel |
| Light slough               | ■ Cleans   | ■ Soaks          |
| Low exudate                | ■ Prevents biofilm/complications | ■ Wounds |

| CHRONIC WOUND – CRITICALLY COLONISED/INFECTED |            | Soak with Solution | Apply Gel |
| Medium/high exudate         | ■ Cleans   | ■ Soaks          |
| Static wound                | ■ Prevents biofilm/complications | ■ Wounds |
| Slough                      |            | 24/7 Action      |

*High risk patient: Co-morbidities such as Diabetes, immuno-compromised, steroidal use, patients with previous wound infection and or biofilm and slough.

Compatible with other dressings
Once opened, Prontosan Solution and Gel can be used for up to 8 weeks (single patient use)
<table>
<thead>
<tr>
<th>STUDY</th>
<th>TYPE</th>
<th>CONCLUSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bellingeri et al., (2016), Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic wound: a single-blind RCT, Journal of Wound Care</td>
<td>RCT</td>
<td>The results of this RCT with 289 subjects confirms the superiority of Prontosan® 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.</td>
</tr>
<tr>
<td>Romanelli M, et al., (2008), Evaluation of the efficacy and tolerability of a solution containing Betaine and PHMB in controlling the bacterial burden of chronic wounds during wound bed preparation</td>
<td>RCT</td>
<td>The results of the RCT with 40 subjects show that the pH value of the wound was significantly (p&lt;0.05) lower and that pain control was achieved (p&lt;0.05) in the Prontosan treatment group compared to the Saline group which was the control.</td>
</tr>
<tr>
<td>Valenzuela et al., (2008), The effectiveness of a 0.1% polyhexanide gel. Rev ROL Enf;31(4):247-52.</td>
<td>RCT</td>
<td>If current thinking, that all chronic wounds are biofilm wounds (Wolcott 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.</td>
</tr>
</tbody>
</table>
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 results.

- Improved patient outcomes, including time to heal
- Helps to prevent complications
- Helps to reduce spend on antimicrobials and antibiotics

How Prontosan Saves You Money

In a model calculation for the UK, 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, $700 per patient.

<table>
<thead>
<tr>
<th>Breakdown of wound care costs</th>
<th>Cost drivers</th>
<th>How Prontosan reduces costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>40% Inpatient costs</td>
<td>Increased number of bed days</td>
<td>Infection rates reduced from 40% to 3%</td>
</tr>
<tr>
<td>40% Nursing time</td>
<td>Length of treatment time</td>
<td>Treatment time reduced from 17 to 13 weeks</td>
</tr>
<tr>
<td>20% Dressing</td>
<td>Cost of dressings</td>
<td>Dressing changes</td>
</tr>
</tbody>
</table>

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.
Quality of Life Case Study Extracts

"The use of Prontosan® Solution and Gel contributed to the \textit{speedy healing} of these diabetic wounds by reducing bioburden. Their use enabled the \textit{painless} removal of sloughy tissue within one week. The patient spoke of \textit{increased confidence} that his wounds would heal, directly as a consequence of using Prontosan."


07/07/2010 \hspace{1cm} 03/09/2010

"The patients quality of life improved with a \textit{reduction in pain} and a \textit{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 \textit{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)

03/09/2009 \hspace{1cm} 10/12/2009

"The benefits in terms of \textit{increased quality of life} for this patient cannot be underestimated and as a result of the \textit{successful wound management} this lady has now started to swim again, is looking forward to a holiday abroad with friends and most importantly is now being considered for the renal transplant list."


01/04/2008 \hspace{1cm} 10/06/2008

"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. \textit{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 \textit{improved the patient's morale} and the results have motivated all nursing staff."


12/04/2006 \hspace{1cm} 14/04/2006

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# Prontosan® Solution and Gel

## Ordering Information

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Size</th>
<th>Pack Size</th>
<th>Product Code</th>
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<tbody>
<tr>
<td>Prontosan Solution</td>
<td>40 ml ampoule</td>
<td>24</td>
<td>400419</td>
</tr>
<tr>
<td></td>
<td>350 ml bottle</td>
<td>10</td>
<td>400431</td>
</tr>
<tr>
<td></td>
<td>1000 ml bottle</td>
<td>10</td>
<td>400432</td>
</tr>
<tr>
<td>Prontosan Gel</td>
<td>30 ml tube</td>
<td>20</td>
<td>400510</td>
</tr>
</tbody>
</table>

**REFERENCES:**
9. Coller, Mark. "Evidence Of The Reduction Of Hospital Acquired Infections (HCAI’s) Following The Introduction Of A Standard Antimicrobial Wound Cleansing Solution To All Surgical Areas Within A Large Acute NHS Trust In The UK". Wounds UK (2014)

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