



# 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.<sup>1</sup>

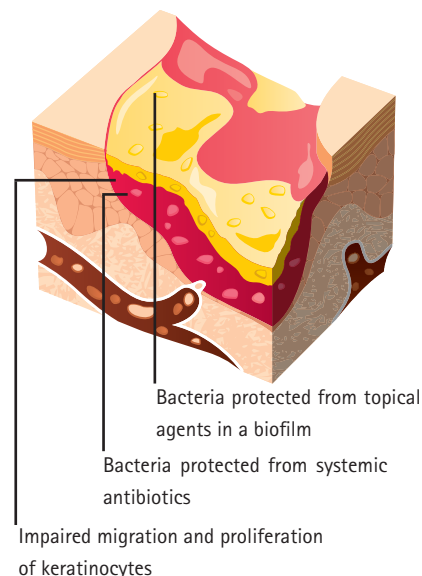
OVER  
**90%**  
OF WOUNDS HAVE  
A BIOFILM<sup>1</sup>

## 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.<sup>2</sup>



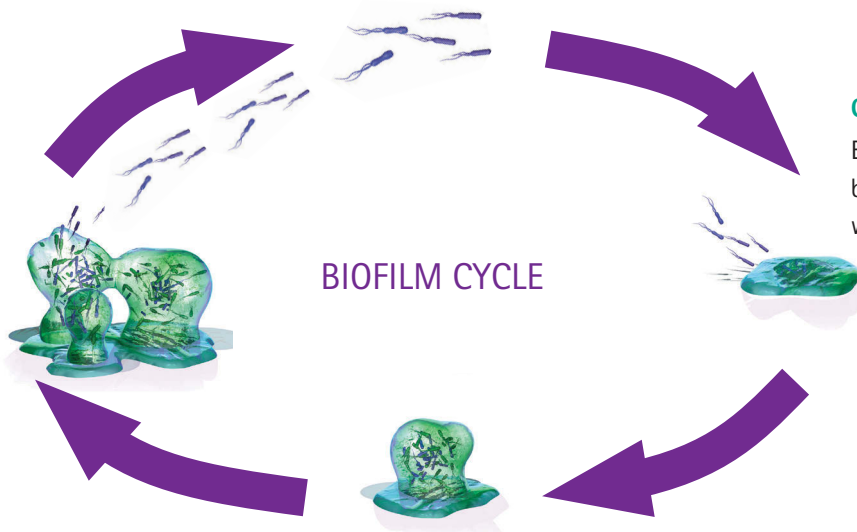
## HOW DO BIOFILMS DEVELOP?<sup>2</sup>

### 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.



### 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

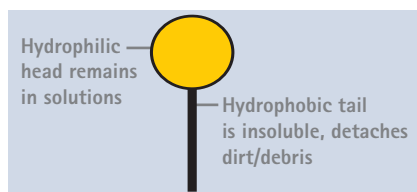
The prevention and management of biofilm in chronic wounds is rapidly becoming a primary objective of wound care, with the presence of biofilm acknowledged as a leading cause of delayed wound healing.<sup>3</sup>

**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**.

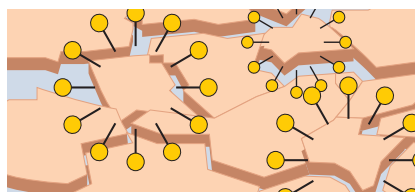
## BETAINE

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

### BETAINE MOLECULE

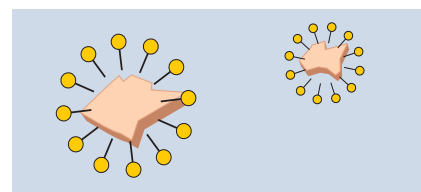


### REDUCES SURFACE TENSION



Supporting softening, loosening and detaching of dirt, debris and biofilm.

### REMOVES AND HOLDS IN SOLUTION

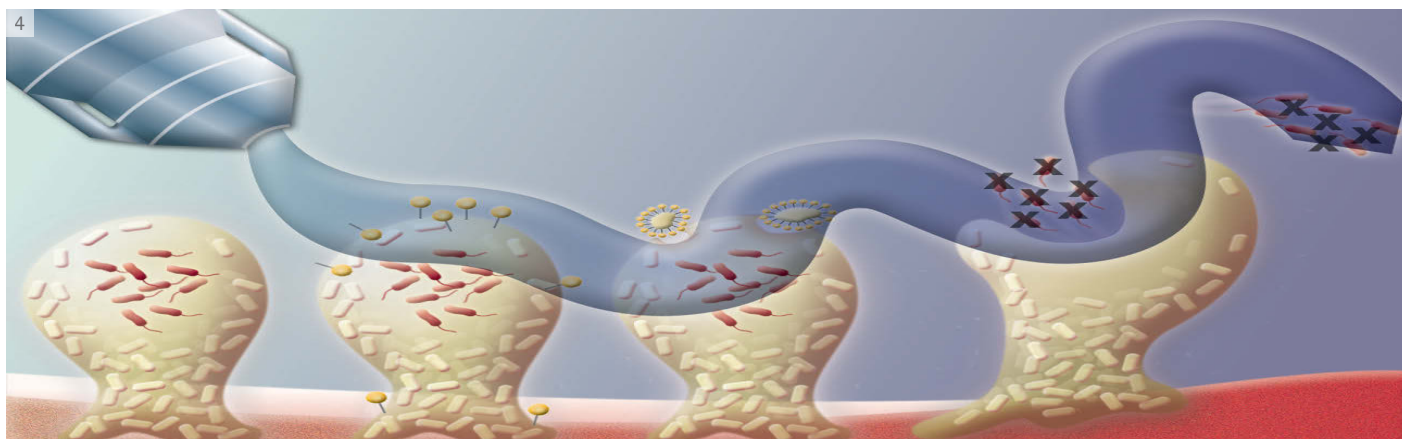


Holds dirt, debris and biofilm in the solution, preventing recontamination.

## 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.<sup>10</sup> 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).



Biofilm present

Mechanical rinsing with  
Prontosan Solution

Betaine disrupts biofilm  
(removes dirt and debris)






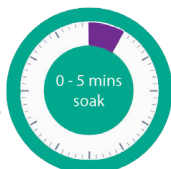




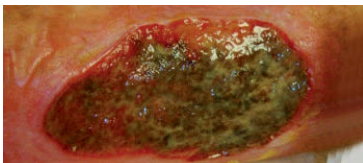
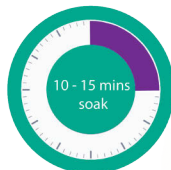

Wound is cleansed, de-sloughed,  
debrided, decontaminated and  
free from biofilm

# Prontosan<sup>®</sup> Breaks the Biofilm Cycle

A proactive approach using a combination strategy of Prontosan<sup>®</sup> Solution and Prontosan<sup>®</sup> 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

DESCRIPTION OF WOUND	OBJECTIVE	HOW TO USE
<b>ACUTE WOUND - SURGICAL PRIMARY &amp; SECONDARY INTENTION HEALING</b>		Rinse with Solution
<ul style="list-style-type: none"> <li>■ High risk patient*</li> <li>■ No slough</li> <li>■ Minimal exudate</li> </ul> 	<ul style="list-style-type: none"> <li>■ Cleans</li> <li>■ Prevents biofilm/complications</li> </ul>	
<b>ACUTE WOUND e.g. trauma</b>		Soak with Solution
<ul style="list-style-type: none"> <li>■ Debris</li> <li>■ Haematoma</li> </ul> 	<ul style="list-style-type: none"> <li>■ Cleans</li> <li>■ Prevents biofilm/complications</li> </ul>	
<b>CHRONIC WOUND - GRANULATING</b>		Soak with Solution Consider Gel
<ul style="list-style-type: none"> <li>■ High risk patient*</li> <li>■ Low exudate</li> </ul> 	<ul style="list-style-type: none"> <li>■ Cleans</li> <li>■ Prevents biofilm/complications</li> </ul>	 + 
<b>CHRONIC WOUND</b>		Soak with Solution Apply Gel
<ul style="list-style-type: none"> <li>■ Light slough</li> <li>■ Low exudate</li> </ul> 	<ul style="list-style-type: none"> <li>■ Cleans</li> <li>■ Prevents biofilm/complications</li> </ul>	 + 
<b>CHRONIC WOUND - CRITICALLY COLONISED/INFECTED</b>		Soak with Solution Apply Gel
<ul style="list-style-type: none"> <li>■ Medium/high exudate</li> <li>■ Static wound</li> <li>■ Slough</li> </ul> 	<ul style="list-style-type: none"> <li>■ Cleans</li> <li>■ Prevents biofilm/complications</li> </ul>	 + 

\*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)

Applicable only to Prontosan products sold in Canada

STUDY	TYPE	CONCLUSION
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	RCT	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.
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	RCT	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 which was the control.
Valenzuela et al., (2008), The effectiveness of a 0.1% polyhexanide gel. Rev ROL Enf;31(4):247-52.	RCT	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 ( $p=0.029$ ).
Cutting K, (2010), Addressing the challenge of wound cleansing in the modern era, British Journal of Nursing, 2010 (Tissue Viability Supplement), Vol 19, No 11	Review	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. 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.
Dissemond J., et al., (2005), Methicilin-resistenter Staphylococcus aureus (MRSA) in chronischen Wunden, JDDG	Review	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.
Andriessen A, Eberlein T (2008), Assessment of a wound cleansing solution in the treatment of problem wounds, WOUNDS; 20(6):171-175	Retro-spective	Wounds (Venous leg ulcers) of patients treated with Prontosan® healed significantly faster ( $p<0.0001$ ) and in more cases (97% versus 89%) than the wounds of patients treated with saline solution or Ringer's solution. Additionally the infection rate for the Prontosan group was lower (13% vs. 3%)
Moller et al., (2008), Experiences in using polyhexanide containing wound products in the management of chronic wounds – results of a methodical and retrospective analysis of 953 cases, Wundmanagement; 3:112-117.	Retro-spective	Treatment resulted in an improvement of 97% and a complete closure of 80% of the wounds. Infection rates declined from 40% to 3%. Prontosan® Wound Irrigation Solution and Gel were compatible with various wound dressings, induced no skin irritations, reduced odor and were accepted by the patients.
Durante et al., (2014), Evaluation of the effectiveness of a polyhexanide and propyl betaine-based gel in the treatment of chronic wounds, Minerva Chirurgica; 69(5):283-292	Observational	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.
Kaehn et al., (2009), In-vitro test for comparing the efficacy of wound rinsing solutions, British Journal of Nursing	In-vitro	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 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 compared with saline solution. The wound antiseptic Octenisept did not seem suitable for wound cleansing because proteins were denatured and became insoluble.
Lopez-Rojas et al., (2016), In vitro activity of a polyhexanide-betaine solution against high-risk clones of multidrug resistant nosocomial pathogens, Enferm Infecc Microbiol Clin 35 (1), 12-19.	In-vitro	Prontosan® has high bactericidal activity against the studied multidrug-resistant pathogens. Furthermore, this bactericidal activity occurs rapidly (1 min), within a much shorter period of time than that recommended by the manufacturer.
Hirsch et al., (2010), Evaluation of Toxic Side Effects of Clinically Used Skin Antiseptics In Vitro, Journal of Surgical Research Volume 164, Issue 2	In-vitro	Due to the cytotoxic effect of some antiseptics on human skin cells, it is advised that health care professionals balance the cytotoxicity of the medication, their antiseptic properties, and the severity of colonization when selecting a wound care antiseptic. Lavasept and Prontosan showed best result regarding antibacterial efficacy and cell toxicity, and should therefore be favored in clinical wound care.
Seipp et al., (2005), Efficacy of various wound irrigants against biofilm, ZFW; 4: 160-164.	In-vitro	As far as the clinical practice of biofilm removal based on moist management practices is concerned, our investigations attest to the superior efficacy of the surfactant and polyhexanide solution compared with isotonic saline or Ringer's solution.



# 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<sup>7</sup>
- Helps to prevent complications<sup>12</sup>
- Helps to reduce spend on antimicrobials and antibiotics<sup>11</sup>

## How Prontosan Saves You Money

In a model calculation for the UK,<sup>11</sup> 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.<sup>8</sup>

Breakdown of wound care costs <sup>5</sup>	Cost drivers	How Prontosan reduces costs
<b>40%</b> Inpatient costs	<ul style="list-style-type: none"> <li>■ Increased number of bed days</li> <li>■ Complication rates</li> </ul>	<ul style="list-style-type: none"> <li>■ Infection rates reduced from 40% to 3%<sup>6</sup></li> <li>■ Inflammatory signs reduced. BWAT Score p=0.0043<sup>7</sup></li> <li>■ Decrease in incidence of reduction in bacterial counts<sup>9</sup></li> </ul>
<b>40%</b> Nursing time	<ul style="list-style-type: none"> <li>■ Length of treatment time</li> </ul>	<ul style="list-style-type: none"> <li>■ Treatment time reduced from 17 to 13 weeks<sup>8</sup></li> <li>■ Wound size reduction. BWAT Score p=0.049. Granulation tissue improvement. BWAT Score p=0.043<sup>7</sup></li> </ul>
<b>20%</b> Dressing	<ul style="list-style-type: none"> <li>■ Cost of dressings</li> <li>■ Frequency of dressing changes</li> </ul>	<ul style="list-style-type: none"> <li>■ Dressing changes<sup>6</sup></li> <li>■ Silver dressings<sup>6</sup></li> </ul>

## 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 **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."

Butters, V and McHugh, J. "A Case Report On The Use Of A Moistening, Cleansing, Surfactant Irrigation Solution And Gel On A Traumatic Wound On A Diabetic Patient In A Busy Acute Department.". European Wound Management Association (2012): 481.



07/07/2010



03/09/2010

"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."

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



03/09/2009



10/12/2009

"The benefits in terms of **increased quality of life** for this patient cannot be underestimated and as a result of the **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."

Hughes, Nicola. "Calciphylaxis – A Successful Outcome In Wound Management Using Prontosan." European Wound Management Association (2008)



01/04/2008



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. **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."

Horrocks, A. "Successful Treatment of two grade 4 pressure ulcers of 5 years duration using Prontosan® Solution and Gel. European Wound Management Association (2006)



12/04/2006



14/04/2006



17/02/2006



17/03/2006

# Prontosan<sup>®</sup> Solution and Gel

## Ordering Information

Product Description	Size	Pack Size	Product Code
Prontosan Solution	40 ml ampoule	24	400419
	350 ml bottle	10	400431
	1000 ml bottle	10	400432
Prontosan Gel	30 ml tube	20	400510

B. Braun of Canada | email: [info@bbraun.ca](mailto:info@bbraun.ca) | telephone: 1-855-822-7286

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10. Kaehn, K Polyhexanide: A Safe and Highly Effective Biocide, Skin Pharmacol Physiol 2010;23(suppl1);7-16
11. Data on file
12. Moore, M 0.1% Polyhexanide-Betaine Solution as an Adjuvant in a Case-Series of Chronic Wounds, Surg Technology International, 2016

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