









PRONTOSAN®

WOUND BED PREPARATION IN 3 STEPS



Control and act Acute and chronic wounds are at risk of becoming infected which can compromise the normal healing pathway, leading to a greater burden on health systems, long term disabilities and an overall reduction of a patient's quality of life.



WOUNDS

There are 400,000 people affected with chronic wounds in Australia contributing to 2.1% of the total national healthcare expenditure. ¹



BIOFILM

Over 90% of chronic wounds contain biofilm with a role in wound infection. ²



INFECTION

50% of chronic wounds are estimated to be infected. ³

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 healing².

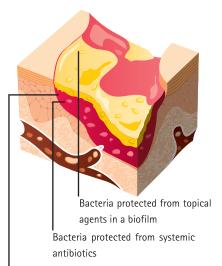
9000 OF WOUNDS HAVE A BIOFILM⁴

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 ⁵.



Impaired migration and proliferation of keratinocytes

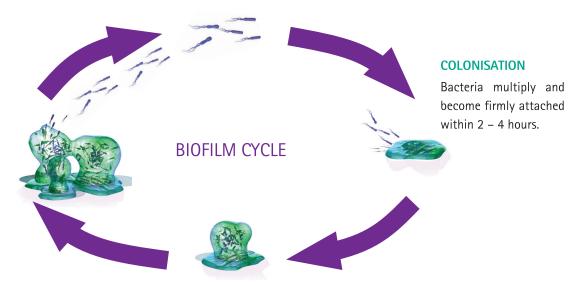
HOW DO BIOFILMS DEVELOP?²

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 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

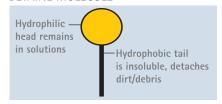
The prevention and management of biofilm in chronic wounds is rapidly becoming a primary objective of wound care, with the presence of biofilm acknowledged as a leading cause of delayed wound healing. ⁶

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

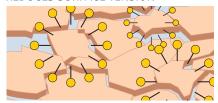
BETAINE

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

BETAINE MOLECULE

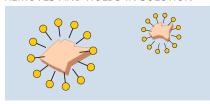


REDUCES SURFACE TENSION



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

REMOVES AND HOLDS IN SOLUTION

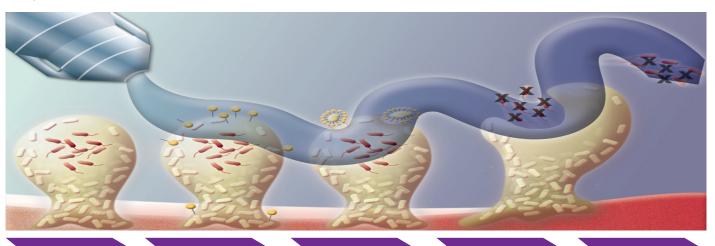


Holds dirt, debris and biofilm in the solution, preventing recontamination.

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 etc⁷. 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 toxicity ^{8, 9, 10}. 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 Prontosan® Solution Betaine disrupts biofilm (removes dirt and debris)

Polyhexanide as adjuvant antimicrobial

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

Prontosan® - only a clean wound can heal

Wound bed preparation and infection prevention are a prerequisite



Breakdown of wound care costs	How Prontosan reduces costs
40% Inpatient costs	 Infection rates reduced from 40% to 3% ¹⁴ Inflammatory signed reduced. BWAT Score p=0.0043 ¹¹ Decrease in incidence of reduction in bacterial counts ¹⁹
40% Nursing time	 Treatment time reduced from 17 to 13 weeks ¹³ Wound size reduction. BWAT score p=0.049. Granulation tissue improvement. BWAT score p=0.043 ¹¹
20% Dressing	 Reduced cost of dressings ¹⁴ Reduced frequency of dressing changes ¹⁴

Prontosan® is a ready to use solution containing 0.1% Betaine (surfactant) and 0.1% Polyhexanide (preservative). The unique combination of Polyhexanide and Betaine have a double effect on the wound bed to create a wound environment optimal for healing. Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel/ Gel X are indicated for cleansing and soaking, and moistening of

acute, chronic, infected wounds, superficial, superficial partial thickness, deep partial thickness burns (also full thickness burns for Prontosan® Wound Gel X), and the prevention of biofilm formation.

Clinical studies prove faster wound healing¹⁴, less complications¹² and increased quality of life¹⁵. Prontosan helps manage infection prevention, cleansing, as well as wound bed moisturising. Prontosan[®] is your partner in preventing and treating the formation of biofilms.

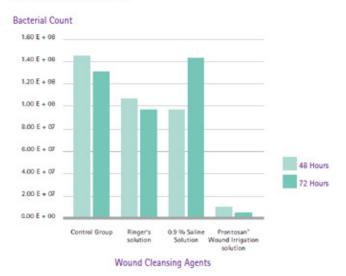
BETAINE

- Particularly high quality tenside
- Effective wound irrigation and cleanser
- Excellent skin tolerance
- Does not dehydrate tissues
- Widely used in different industries

POLYHEXANIDE

- Excellent skin tolerance
- Skin and mucous membranes do not dry out
- Non-toxic
- Hypoallergenic
- No tissue irritation
- No resorption

EFFECTS OF PRONTOSAN* WOUND IRRIGATION SOLUTION ON METHICILLIN RESISTANT STAPHYLOCOCCUS AUREAS BIOFILMS AFTER 48 & 72 HOURS²²



KEY HIGHLIGHTS OF PRONTOSAN

- Suitable for long term use
- No inhibition of granulation tissue unlike antiseptics
- Compatible with all commonly used wound dressings 18,24
- Suitable for use on children and newborns and is well tolerated³⁵
- No contraindications with silicone foams, polyurethane foams, silver dressings, and calcium alginates
- Well tolerated, non-irritant, less pain and less odour^{25,26}

Prontosan® Wound Irrigation Solution

Wound Bed Preparation Taken Seriously

Prontosan® Wound Irrigation Solution is indicated for cleansing, rinsing and moisturising acute and chronic wounds.

Prontosan® Wound Irrigation Solution is also ideal for moistening encrusted dressings, or bandages prior to removal.

Prontosan® can also be used in combination with the V.A.C. VeraFlo* negative pressure wound therapy with the installation of Prontosan®.

INDICATIONS

For cleansing, moisturising and decontaminating skin wounds and burns:

- Traumatic wounds
- Postoperative wounds
- Chronic ulcers (e.g. venous, diabetic, arterial or pressure injuries)
- Thermal wounds
- Chemical wounds (acid and alkali induced)
- Radiation induced wounds



Prontosan® Wound Irrigation Solution

Gauzes or pads soaked with Prontosan Wound Irrigation Solution can be used for cleansing as required. Application should be carried out frequently enough for all coatings and necrosis to be readily removed and to achieve an optically clean wound. This is a good precondition for normal wound healing.

ADVANTAGES

- Management and prevention of biofilm reformation^{1,2}
- Helps to prevent infections¹²
- Improved patient outcomes, including time to heal¹¹
- Well-known substances with low allergenic potential¹⁷
- Can be used up to 8 weeks after first opening (Prontosan® Wound Spray can be used up to 12 months after opening). (Prontosan® Solution 40ml ampoule is single use only)
- Prontosan® Solution is single patient use



Prontosan® Wound Spray

Prontosan® Wound Spray consists of the same ingredients as Prontosan® Wound Irrigation Solution but comes in a spray format. It supports rapid healing by effective cleansing and moistening of superficial wounds and burns, including clotted or encrusted dressings. It reduces risk of infection and optimal healing conditions are generated. Suitable for peristomal skin complications, around SPC sites, skin tears, lacerations and abrasions.

HINTS AND TIPS

PAINLESS DRESSING CHANGES WITH PRONTOSAN®

Dressings are often encrusted and stick to wound surfaces. If attempted to be removed when dry, new injuries often arise with the additional risk of infection, which delays the healing process. In cases where it is difficult to remove, intensive moistening of the dressings with Prontosan® Wound Irrigation Solution is advisable until they can be gently removed.

Prontosan® Wound Gel & Prontosan® Wound Gel X

Wound Bed Preparation Taken Seriously

After the use of Prontosan® Wound Irrigation Solution, the use of Prontosan® Wound Gel/Gel X act as an effective barrier to reduce colonisation and to decontaminate the wound bed between dressing changes.^{27,28}

Not only does Prontosan® Wound Gel/Gel X prevent the reformation of biofilm, it also keeps the wound moist.

INDICATIONS

For cleansing, moisturising and decontaminating wounds and burns:

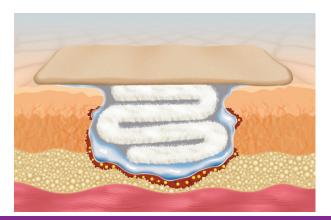
- Traumatic wounds
- Postoperative wounds
- Chronic ulcers (e.g. venous, diabetic, arterial or pressure injuries)
- Thermal wounds
- Chemical wounds (acid and alkali induced)
- Radiation induced wounds
- Superficial, superficial and partial thickness, deep partial thickness burns (Prontosan® Gel)
- Full thickness burns (Prontosan® Gel X)

WHEN TO USE WHICH GEL



Prontosan® Wound Gel

For the application in deep or tunnelling wounds, fill the wound cavity and difficult to access areas with a 3-5mm layer of gel and cover with a primary dressing.



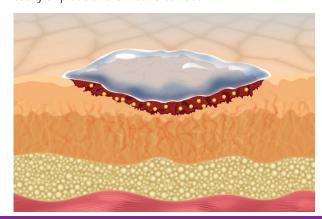
ADVANTAGES^{22,23,24,26,29,30}

- Removes & prevents biofilm
- Prevents infections
- Reduces healing time
- Painless dressing changes
- Well-known substances with low allergenic potential
- Compatible with commonly used wound dressings
- Can be used up to 8 weeks after first opening (single patient use)
- Remains on wound bed between dressing changes for up to 7 days



Prontosan® Wound Gel X

For larger surface area wounds, apply a 3-4mm thick layer and cover with a primary dressing. When large quantities are required where Prontosan® Gel is too fluid and may easily drip out of the wound surface.



HINTS AND TIPS

All wounds should in principle first be rinsed and cleansed with Prontosan® Wound Irrigation Solution, Prontosan® Gel / Gel X remain on wound bed until the next dressing change. It therefore has a long lasting effect.

Prontosan® Debridement Pad

SOFT MECHANICAL REMOVAL OF SLOUGH AND DEBRIS

Designed for soft mechanical debridement of slough and debris. The Prontosan Debridement Pad removes and binds slough and debris and assists with effective wound bed preparationnew granulation tissue is left intact.

FEATURES

- Good cleansing and debridement due to microfiber technology
- Soft debridement, no tissue irritation31
- Unique droplet shape to allow debridement of cavities and areas difficult to reach
- Blister packaging to allow safe and aseptic soaking of the pad prior to use
- Produces good results even with scaly and necrotic coatings³²

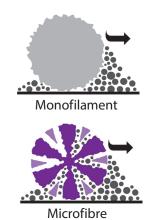


Micro Technology, Maximum Cleansing

The Prontosan® Debridement Pad uses the latest technology in clean sing-microfibres. Microfibres are very small and utilise 'electrostatic forces' to attract even the smallest particles to them.

Each microfibre has a multiple strand structure, allowing for many more particles of slough and debris to be removed from the wound be dand bound to each microfibre within the pad; not just brushed away as with traditional, much larger, monofilament fibres.

 $The rear emillions of microfibres in each Prontosan ^{\circ} De bridement Padformagnified de bridement power.$



Experts in Wound Cleansing

A NEW ADDITION TO COMPLETE THE PRONTOSAN® RANGE

BEFORE AND AFTER USING THE PRONTOSAN® DEBRIDEMENT PAD







Before debridement

After a single debridement

3 weeks post debridement

HOW TO USE FOR BEST RESULTS

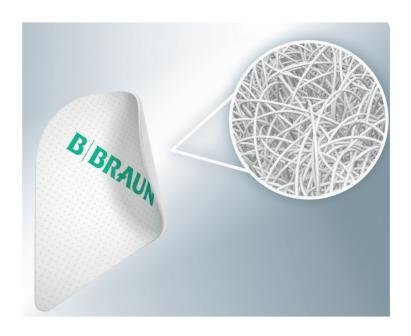
- TIP
- B. Braun branded side faces away from the wound bed
- $\bullet \ Prontosan°Solution (as soak or rinse) can be used beforehand$
- Open the packaging, using the integrated tray to moisten (with Prontosan Solution*), covering the microfibre side of the pad
- Applying light pressure, use circular or sweeping motions over areas of slough and debris
- 3 Irrigate (with Prontosan Solution*) to cleanse
- Apply Prontosan Gel X to help prevent biofilm formation and apply dressings as appropriate**







After use of Prontosan® Debridement Pad













HOW TO USE PRONTOSAN®

Prontosan® Wound Irrigation Solution

Remove the dressing carefully and assess the dressing. If encrusted, please refer to page 6 for recommendations on painless dressing changes.

Soak a swab with Prontosan® Wound Irrigation Solution and clean the wound, the edge and the surrounding skin from wound exudate.

Soak gauze pads in Prontosan® Wound Irrigation Solution and apply it to the wound and beyond the wound edge. Leave it on wound for appropriate time.*

* Refer to the next page for recommendations on application time according to the wound type.



Dressing Change

RINSING/CLEANSING

DEBRIDEMENT

Prontosan® Debridement Pad

If debridement is required, remove the gauze pads and rinse the wound. Soak the Debridement Pad with Prontosan® Wound Irrigation Solution.

Use sterile gloves amd take the Debridement Pad, carry out the mechanical debridement in order to remove surface debris, biofilm and devitalised tissue.



Assess the wound.

Perform wound edge protection with Askina® Barrier Film.

Apply Prontosan® Wound Gel/Gel X.

Prontosan® Wound Gel

Prontosan® Wound Gel X



Liquid: ideal for cavities and deep tunnelling wounds, fistulas.



Highly viscous: ideal for large surface area wounds, burns and leg ulcers.









Prontosan® Breaks the Biofilm Cycle

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

- Reduce the biofilm burden (Prontosan® Solution)³⁰
- Prevent reconstitution of the biofilm (Prontosan® Gel/ Gel X)

Appropriate Time for Appropriate Wound

DESCRIPTION OF WOUND

OBJECTIVE

HOW TO USE

ACUTE WOUND - SURGICAL PRIMARY & SECONDARY INTENTION HEALING

Rinse with Solution

- High risk patient*
- No slough
- Minimal exudate



- Cleans
- Prevents biofilm/complications



ACUTE WOUND e.g. trauma

- Debris
- Haematoma



- Cleans
- Prevents biofilm/complications



Soak with Solution

CHRONIC WOUND - GRANULATING

Soak with Solution Consider Gel X

- High risk patient*
- Low exudate



- Cleans
- Prevents biofilm/complications





CHRONIC WOUND

Soak with Solution Apply Gel X

- Light slough
- Low exudate



- Cleans
- Prevents biofilm/complications



Soak with Solution



CHRONIC WOUND - CRITICALLY COLONISED/INFECTED

Medium/high exudate

- Static wound
- Slough



- Cleans
- Prevents biofilm/complications





Apply Gel X

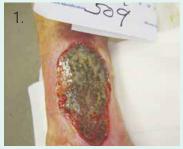
Prontosan has proven efficacy after as little as 1 min soak time. The longer you leave it the better the result. There is no limit to how long Prontosan® can be left on the wound^{21.}

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

Prontosan® Case Studies by wound type

VENOUS LEG ULCER - CASE STUDY 1

Responsible person for treatment	Liz Ovens, BSc, RN, DN, Clinical Service Lead Tissue Viability.
Institution	Hillingdon Community Health, Hillingdon NHS, Complex Wound Clinic, CWC London, United Kingdom.
Gender (female, male)	Female
Age of Patient (year)	1926
Past Medical History	Chronic Lymphoid Leukemia. There was no active treatment. Bilateral Knee Replacement, Aortic Stenosis, Bilateral stripping Varicose Veins, Recurrent Leg Ulcer, Hiatus Hernia
Wound Diagnosis	Within 3 days there was a noticeable difference in the wound bed. The raised shiny surface was no longer present. The pain score had reduced to 3 out of 10 and four layer bandaging was commend and tolerated and frequency of dressings was reduced to twice weekly. ³³
Localisation of Wound	Left lateral Venous Leg Ulcer (VLU)
Age of Wound	Six months
Previous treatment of wound	Multiple courses of broad spectrum antibiotics. Topical antiseptic hydrofibre dressing, support bandaging toe to knee. Required daily dressings to manage exudate and strike through.
Reason for treatment change	Several previous courses of antibiotics had proved unsuccessful and the wound swab demonstrated no bacterial growth. She had a high pain score of 8 out of 10 and was unable to tolerate high compression therapy and taking Co-Dydramol four times daily.
Dressing Change Frequency	 Commenced dressings three times weekly Irrigating then soaking wound with Prontosan® Wound Irrigation Solution for 10 minutes Applying Prontosan® Gel to wound bed Applying Hydrofibre Ag and multi-layer Hydrofibre to absorb exudate Continued support bandaging as before
Other products used	Co-Dydramol up to 8 daily, Diazepam 5mgs OD, Omeprazole 20mgs OD, Calcium Carbonate and Calciferol 1.5g and 10 mcg.
Outcome (final comment)	It appears that the combination of the antimicrobial effect of PHMB and the cleansing effect of Betaine disturbed the biofilm layers thus reducing bioburden. The cost of wound management was reduced with only weekly visits by the District Nurses being required compared to daily visits prior to intervention, and through reduced use of antibiotics.



03.03.2009

The wound to the left lateral aspect measured 38 sq cms with 100% slough and covered in a glassy sticky structure that lay proud of the wound bed and had green malodorous exudate.



07.09.2009

Evidence of approximately 25% granulation tissue and less peri-ulcer inflammation.



17.09.2009

Two weeks after initiation of treatment regime, the wound bed had reduced in size to 34 cms sq and had 50% granulation tissue.



10.12.2009

12 weeks later the wound measured 16 cm sq with 98% granulation and required weekly dressings.

DIABETIC FOOT ULCER - CASE STUDY 2 20

Responsible person for treatment	Lorna Jarrett Advanced Diabetes Podiatrist
Institution	Metabolic Unit, Western General Hospital Crewe Road South, Edinburgh HH4 2XU
Gender (female, male)	Male
Age of Patient (year)	1966
Past Medical History	Type 1 Diabetes, Chronic pancreatitis and ulcerative colitis requiring bowl resection surgery
Wound Diagnosis	Neuropathic ulcer
Localisation of Wound	Right heel
Reason for treatment change	Prescence of Staphylococcus Aureus
Dressing Change Frequency	Twice per week
Other products used	Prontosan® Irrigation Solution Prontosan® Wound Gel SIlicone Foam Heel Dressing Darco boot with off loading insole
Treatment	Sterile gauze was soaked in Prontosan® Irrigation Solution then applied to the ulcer for 10 minutes in order to loosen slough, making it easier to remove sharp debridement. Prontosan® Gel was applied to ulcer with a silicone foam heel dressing to manage exudate.
Outcome (final comment)	The wound healed rapidly achieving complete closure in an eight week period. As the patient is self employed, prolonged absence from work could have had serious financial implications. The patient was able to resume work and his every day activities and he reported that this had a positive impact on his quality of life. The use of Prontosan® Irrigation Solution and Prontosan® Gel appears to have played a significant role in the speed of resolution of this diabetic foot ulcer resulting in a cost effective, positive patient outcome.



A shared care dressing regime was arranged with the practice nurse on a twice per week basis.



A review of the ulcer one week later demonstrated a marked reduction in slough, swelling and exudate. At each subsequent visit a 10 minute soak with Prontosan® Irrigation Solution was used prior to sharp debridement. The ulcer was then re-dressed with Prontosan® Gel and a silicone foam heel. Two weeks later the heel is completely free of slough and beginning to granulate.



Picture illustrated continued healing.



Picture taken eight weeks later after initial presentation at the diabetic foot clinic, shows complete ulcer closure.

FAQ Prontosan® Range

WHAT IS PRONTOSAN® MADE OF?

All Prontosan® products contain a Betaine surfactant, Polihexanide (PHMB) and purified water. Additionally, Prontosan® Wound Gel and Prontosan® Wound Gel X contain glycerol and hydroxyethycellulose.

WHAT ARE THE ADVANTAGES OF PRONTOSAN®?23,24,25,30,34

Prontosan® - the unique combination of Betaine and Polihexanide:

- reduces healing time
- removes and prevents biofilm
- prevents infections
- facilitates gentle dressing changes
- is compatible with commonly used dressings

WHICH TYPE OF WOUNDS CAN BE TREATED WITH PRONTOSAN®?

Prontosan® can be used for the treatment of acute wounds, chronic wounds, superficial, superficial partial thickness and deep partial thickness burns. (Prontosan® Would Gel X is also indicated for full thickness burns).

DOES PRONTOSAN® HELP WITH DEBRIDING, AND IF SO, HOW?

Yes. Betaine helps to remove wound coatings including slough and necrotic tissue by softening, loosening and subsequently detaching them.³⁵

WHAT IS THE SHELF LIFE OF PRONTOSAN® PRIOR TO OPENING?

Prontosan® Wound Irrigation Solution, Prontosan® Wound Gel & Prontosan® Wound Gel have a shelf life of 3 years.

WHAT IS THE SHELF LIFE OF PRONTOSAN® AFTER FIRST OPENING?

8 weeks for the whole Prontosan® range (single patient use), except for Prontosan® 40ml ampoule is single use only. Prontosan® Wound spray can be used up to 12 months after opening. IMPORTANT: Prontosan® Solution does NOT need to be refridgerated to maintain shelf life. It can be warmed up to body temperature before using.

CAN PRONTOSAN® WOUND IRRIGATION BE USED FOR ORTHOPAEDIC SURGERIES?

Yes. Several users reported good clinical results in using Prontosan® as rinsing solution for orthopaedic surgeries (case reports). Care has to be taken in case of partial joint replacement where intact hyaline cartilage is still present (contraindication). For total joint replacements (hip and knees) the cartilage is completely removed and therefore the use of Prontosan® is possible.

WHAT PRESSURE IS GENERATED BY SQUEEZING THE PRONTOSAN® WOUND IRRIGATION SOLUTION BOTTLE (350ml)?³⁶

The 350ml bottle generates up to 7psi (pounds per square inch) of pressure. According to Medtech Insight 1997 (Chapter 3, pp71-72) report, a PSI between 4-15 is required for adequate wound irrigation and cleansing. Spray bottles can generate only up to 1.5PSI. Prontosan® does not need to be transferred to another container (such as a syringe) to produce adequate PSI pressure.

FOR HOW LONG CAN A WOUND BE TREATED WITH PRONTOSAN®?

There is no limit set for the treatment duration with Prontosan® Wound Irrigation Solution.

HOW EXTENSIVE IS THE CLINICAL EXPERIENCE WITH PRONTOSAN®?³⁸

Hundreds of thousands of patients have been treated with Prontosan® worldwide since is launch. A dedicated Scientific Evidence Brochure has been created to document the efficency and efficacy of Prontosan®.

IS PRONTOSAN® WOUND IRRIGATION SOLUTION AND PRONTOSAN® WOUND GEL/GEL X COMPATIBLE WITH SILVER DRESSINGS (IONIC AND NANOCRYSTALLINE)?

Yes. Prontosan® Wound Irrigation can be used with Silver Dressings. Studies and test reports (Test report on file - Brill L13.0111.1 - can be requested by our local marketing) document no degradation of functionality of both the irrigation solution or the dressing.¹⁴

IS THERE ANY INTERACTION BETWEEN PRONTOSAN® AND FOAM OR SILICONE DRESSINGS?

Compatibility tests and many years of usage have shown there is no interaction or limitations in use between Prontosan® and foam or silicone dressings, they can be perfectly combined in treatment. The combined use of Prontosan® with foam or silicone has been carefully monitored. No difference or effects on the dressings has been noticed (loss of material structure, loss of integrity of the material and the surfaces, or loss of consistency of the material).¹⁸

Prontosan® Product Details



PRODUCT	PACK SIZE	PRODUCT CODE
Prontosan® Irrigation Solution		
40 ml ampoule	30	400419
350 ml bottle	10	400431
1000 ml bottle	10	400432
75 ml spray bottle	20	400565



PRODUCT	PACK SIZE	PRODUCT CODE
Prontosan® Wound Gel - 30ml	20	400510
Prontosan® Wound Gel X - 50gm	20	400523



PRODUCT	PACK SIZE	PRODUCT CODE
Prontosan® NPWT Instillation Adapter, sterile (compatible with V.A.C VeraFlo™). Use with the Prontosan® 1 litre Irrigation Solution	10	3908437



PRODUCT	PACK SIZE	PRODUCT CODE
Prontosan® Debridement Pad 12.76 cm x 9.2cm (80cm²)	10	3908457
Prontosan® Debridement Pad 12.76 cm x 9.2cm (80cm²)	3	3908456

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