# Reduce Post Surgical Site Infections

## BerbereX®


**BerbereX®** Wound Cleanser is intended for use in clinical environments and home care to facilitate cleansing of debris, exudate, organic material including micro-organisms from wounds such as pressure ulcers, diabetic foot ulcers, post-surgical wounds, and burns.

**BerbereX®** is a safe and non-irritating antimicrobial wound solution that has broad-spectrum antimicrobial properties. Its unique and patented formulation resolves pathogenic flora and helps to decolonize the wound, yet unlike many antimicrobials, does not impair healing.

**BerbereX®** helps to overcome obstacles to healing that are caused by alkaline pH in chronic wounds such as diabetic ulcers and pressure ulcers, but has no known side effects.

**BerbereX®** is simple to use, requires no significant changes in current wound care protocols, and promotes healing of acute and chronic wounds.

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# How does it work?


## ☑ Antimicrobial

Benzethonium Chloride has a long history of use. It only requires a short contact time to be effective against many types of microorganisms, including a large variety of gram-positive and gram-negative bacteria. In a clinical antimicrobial performance assay BerbereX® Wound Cleanser showed efficacy against highly virulent strains of antibiotic-resistant bacteria that were collected from hospital patients. Upon contact it inhibited all strains of Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), Group B Streptococcus (B-Strep) and E. Coli.

## ☑ pH Balancing

Clinical science has shown that the healing of chronic wounds such as diabetic ulcers and pressure ulcers requires a slightly acidic pH. BerbereX® Wound Cleanser has a pH 4.7, which helps to overcome the effects of alkaline pH that are normally found in such wounds.

## ☑ Promotes Healing

Allantoin promotes healthy skin by improving epithelialization and healthy new tissue growth. Use of BerbereX® Wound Cleanser facilitates removal of debris, excess exudate and necrotic tissue fragments.  It reduces infection, promotes a moist wound environment, and helps to maintain wound pH in a desirable range.  All of these are essential components for a successful recovery from wounds.

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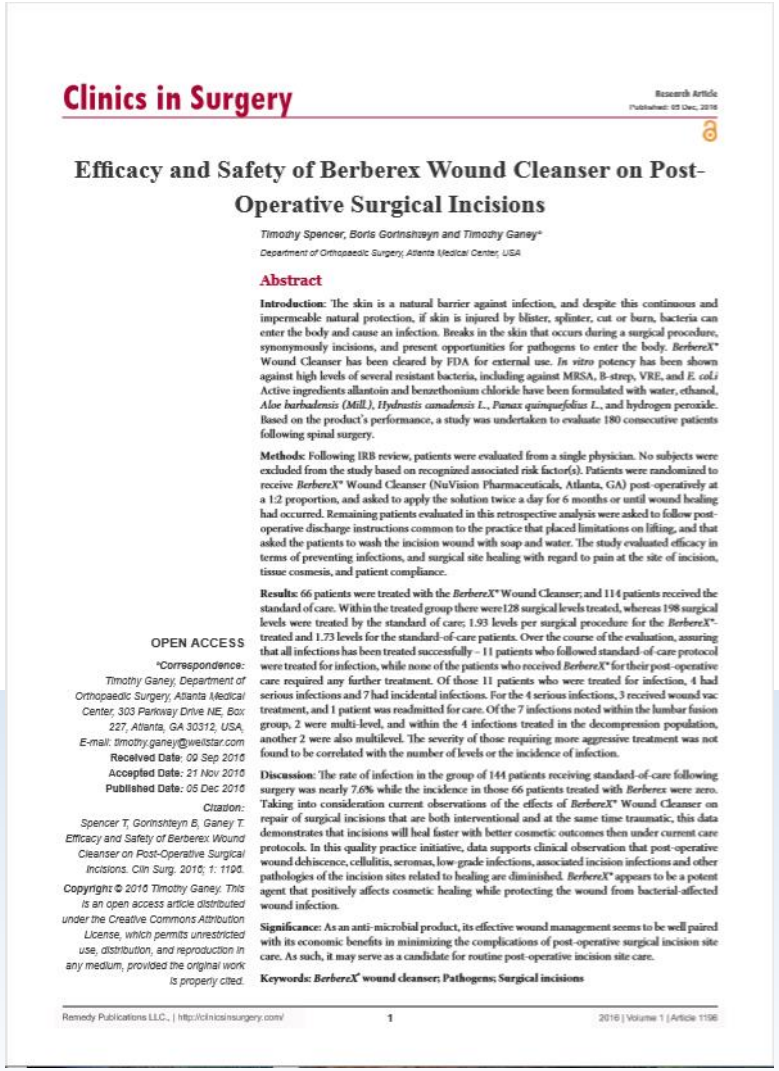
# *Efficacy and Safety of Berberex Wound Cleanser on Post Operative Surgical Incisions*

*Study to evaluate 180 consecutive patients following spinal surgery.*



Clinics in Surgery

Research Article

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## Efficacy and Safety of Berberex Wound Cleanser on Post-Operative Surgical Incisions

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**Abstract**

**Introduction:** The skin is a natural barrier against infection, and despite this continuous and impermeable natural protection, if skin is injured by blister, splinter, cut or burn, bacteria can enter the body and cause an infection. Breaks in the skin that occurs during a surgical procedure, synonymously incisions, and present opportunities for pathogens to enter the body. *BerbereX®* Wound Cleanser has been cleared by FDA for external use. *In vitro* potency has been shown against high levels of several resistant bacteria, including against MRSA, B-strep, VRE, and *E. coli* Active ingredients allantoin and benzethonium chloride have been formulated with water, ethanol, *Aloe barbadensis (Mill.)*, *Hydrastis canadensis L.*, *Panax quinquefolius L.*, and hydrogen peroxide. Based on the product's performance, a study was undertaken to evaluate 180 consecutive patients following spinal surgery.

**Methods:** Following IRB review, patients were evaluated from a single physician. No subjects were excluded from the study based on recognized associated risk factor(s). Patients were randomized to receive *BerbereX®* Wound Cleanser (NuVision Pharmaceuticals, Atlanta, GA) post-operatively at a 1:2 proportion, and asked to apply the solution twice a day for 6 months or until wound healing had occurred. Remaining patients evaluated in this retrospective analysis were asked to follow post-operative discharge instructions common to the practice that placed limitations on lifting, and that asked the patients to wash the incision wound with soap and water. The study evaluated efficacy in terms of preventing infections, and surgical site healing with regard to pain at the site of incision, tissue cosmesis, and patient compliance.

**Results:** 66 patients were treated with the *BerbereX®* Wound Cleanser; and 114 patients received the standard of care. Within the treated group there were128 surgical levels treated, whereas 198 surgical levels were treated by the standard of care; 1.93 levels per surgical procedure for the *BerbereX®*-treated and 1.73 levels for the standard-of-care patients. Over the course of the evaluation, assuring that all infections has been treated successfully – 11 patients who followed standard-of-care protocol were treated for infection, while none of the patients who received *BerbereX®* for their post-operative care required any further treatment. Of those 11 patients who were treated for infection, 4 had serious infections and 7 had incidental infections. For the 4 serious infections, 3 received wound vac treatment, and 1 patient was readmitted for care. Of the 7 infections noted within the lumbar fusion group, 2 were multi-level, and within the 4 infections treated in the decompression population, another 2 were also multilevel. The severity of those requiring more aggressive treatment was not found to be correlated with the number of levels or the incidence of infection.

**Discussion:** The rate of infection in the group of 144 patients receiving standard-of-care following surgery was nearly 7.6% while the incidence in those 66 patients treated with *Berberex* were zero. Taking into consideration current observations of the effects of *BerbereX®* Wound Cleanser on repair of surgical incisions that are both interventional and at the same time traumatic, this data demonstrates that incisions will heal faster with better cosmetic outcomes then under current care protocols. In this quality practice initiative, data supports clinical observation that post-operative wound dehiscence, cellulitis, seromas, low-grade infections, associated incision infections and other pathologies of the incision sites related to healing are diminished. *BerbereX®* appears to be a potent agent that positively affects cosmetic healing while protecting the wound from bacterial-affected wound infection.

**Significance:** As an anti-microbial product, its effective wound management seems to be well paired with its economic benefits in minimizing the complications of post-operative surgical incision site care. As such, it may serve as a candidate for routine post-operative incision site care.

**Keywords:** *BerbereX®* wound cleanser; Pathogens; Surgical incisions

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**Table 1:** Patients were followed over the course of care and the data.

| | *BerbereX®* Wound Cleanser | Standard Care |
|---|---|---|
| Patients | 66 | 114 |
| Number of Levels | 128 | 198 |
| Procedure (levels) | | |
| Kyphosis | 6 (8) | 5 (5) |
| Lumbar Fusion [Inf] | 21(38) | 50(91) [7] |
| Laminectomy | 17(29) | 13(17) |
| Cervical Fusion | 20(49) | 22(41) |
| Decompression | 2(4) | 28(44) [4] |
| Infections [Inf] | 0 | 11 |

( ) # of levels [ ] # of infections

**RESULTS:**

"66 patients were treated with the BerbereX® Wound Cleanser; and 114 patients received the standard of care. Within the treated group there were128 surgical levels treated, whereas 198 surgical levels were treated by the standard of care; 1.93 levels per surgical procedure for the BerbereX®treated and 1.73 levels for the standard-of-care patients. Over the course of the evaluation, assuring that all infections has been treated successfully – 11 patients who followed standard-of-care protocol were treated for infection, while none of the patients who received BerbereX® for their post-operative care required any further treatment. Of those 11 patients who were treated for infection, 4 had serious infections and 7 had incidental infections. For the 4 serious infections, 3 received wound vac treatment, and 1 patient was readmitted for care. Of the 7 infections noted within the lumbar fusion group, 2 were multi-level, and within the 4 infections treated in the decompression population, another 2 were also multilevel."

# Post Surgical Ulnar Nerve Decompression

50 year old male following Ulnar Nerve Decompression Surgery


3 days after surgery. Prior to first BerbereX ® treatment.

After 48 hours of Berberex treatment every 12 hours. Patient was able to discontinue Vicodin.

17 days after surgery. Patient only received 4 treatments of Berberex over 2 day period..

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# Post Surgical Acromioclavicular Joint Separation Surgery

31 year old male following  acromioclavicular joint separation surgery.


5 days after surgery. Prior to first BerbereX® treatment.

After 7 days of applying BerbereX every 12 hours;.

At the end of 2nd week of applying BerbereX;  Every 12 hours 1st week and once per day during 2nd week; 19 days since surgery

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# Non-healing Post Surgical Amputation

74 year old male paraplegic with history of Type I diabetes. Patient had a 5th toe amputation due to chronic, non-healing ulcer that formed as a result of uric acid deposition and unsuccessful treatments.


Figure 2 following 13 Weeks, Antibiotics, NPWT, HBOT

Wound was not healing. Treatment with BerbereX ® started.

Saturated with BerbereX ® prior to dressing changes..


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6 weeks

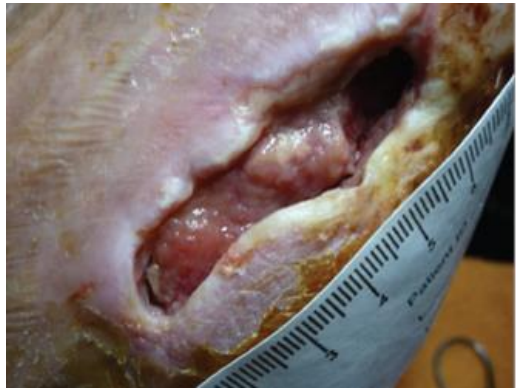

9 weeks


12 weeks


16 weeks

# Non-healing Diabetic Wound

**1 Week**



**4 Weeks**

**6 Weeks**

**8 Weeks**

Available in 4 oz
and 16 oz bottles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