

# BioclyNSE

The “rinse-less” Wound Irrigation



**CLYRA™**  
Medical Technologies Inc

# The High Price of Infection and Chronic Wounds

In American hospitals alone, the Centers for Disease Control (CDC) estimates that Healthcare - Associated Infections (HAIs) account for an estimated 1.7 million infections and 99,000 associated deaths each year.\*

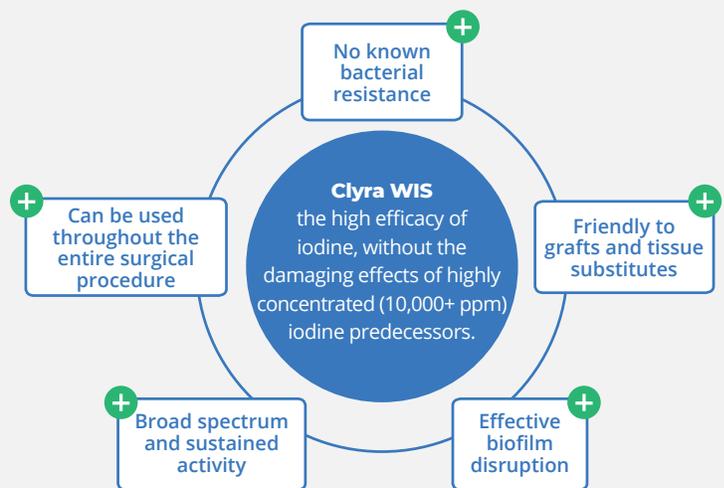
**X**  
**Traditional Antimicrobials**  
Can be effective, but are constantly walking a tightrope between exposure, effectiveness and toxicity. E.g. Lugol's iodine solution.

**X**  
**Traditional Surfactants**  
Effective at disrupting biofilms but not efficacious against pathogens. Toxicity concerns.

**✓**  
**Clyra Wound Irrigation Solution "Bioclyne"**  
Innovative copper-iodine ion complex technology (~250 ppm free iodine) that disrupts biofilm, is highly effective against pathogens and has no harmful effects on host tissue cells.

**Bioclyne** is the first efficacious, safe, long-acting wound irrigation solution that **can be used throughout the entire surgical procedure, with no need to rinse out.**

**✓**  
This clear, odorless, non-irritating solution is FDA 510(k) cleared and indicated for **all wound types.**



## Bioclyne: An Effective Approach to Biofilm Reduction

**10% of bacteria** are planktonic, meaning free-floating

**90% of bacteria** exist in a biofilm structure



- ✓** Effective against biofilm with **2.0 - 2.5 log reduction**<sup>1</sup>
- ✓** **Extremely high antimicrobial activity (preservative action): >99.999% kill rate (>5 log reduction)** with sustained efficacy **up to 3 days**<sup>2,3</sup>.
- ✓** No more settling for a 2 minute "rinse".
- ✓** No need for a five minute soak or subsequent rinse-out.
- ✓** **Bioclyne** is safe to be used throughout the procedure and **does not need to be rinsed out.**

\*<https://patientcarelink.org/improving-patient-care/healthcare-acquired-infections-hais/>

## Bioclynse Indication

The subject device is a wound management and cleansing solution that is intended for use by healthcare professionals for cleansing, irrigating, moistening and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wounds such as:

- 1st and 2nd degree burns
- stage I - IV pressure ulcers
- diabetic ulcers
- stasis ulcers
- abrasions and minor skin irritations
- post-surgical wounds
- grafted and donor sites

Bioclynse can be used to moisten and lubricate absorbent wound dressings (e.g. gauze).

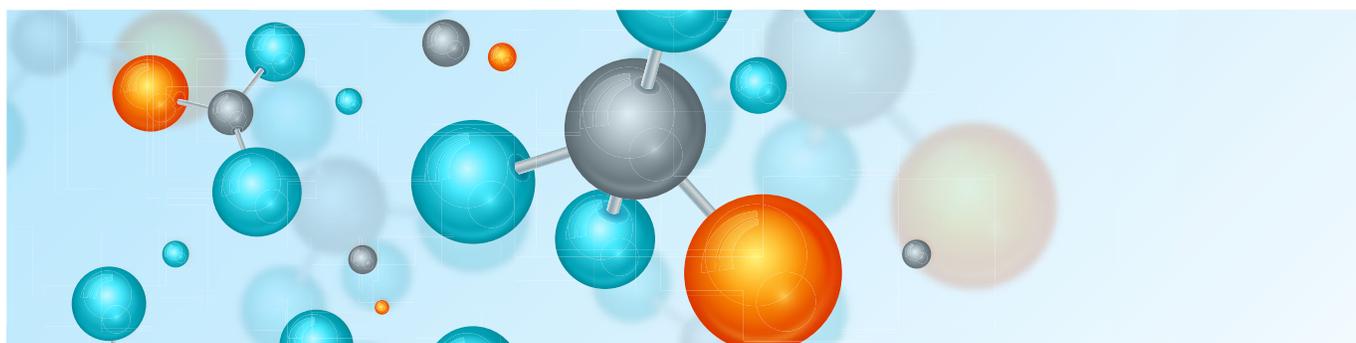
## Instructions for Use

- Apply throughout the procedure to full thickness or post-surgical wounds
- May be used with a vented spike irrigation set prior to hanging for application
- No need to rinse
- Can be used with static or pulsed lavage, ultrasonic debridement and negative pressure wound therapy
- Can be reapplied when required
- For single use only
- Not for injection, IV, or ophthalmologic use
- Do not use if there is a history of allergy to any of the ingredients.

## Safe

- ✓ **Non-irritant<sup>3</sup>**
- ✓ **Non-sensitizing<sup>4</sup>**
- ✓ **Non-cytotoxic<sup>5</sup>**
- ✓ **Non-pyrogenic<sup>6</sup>**
- ✓ **Wound tissue friendly<sup>7</sup>**

## How Does Bioclynse Work?



The mechanical action of fluid moving across the wound aids in the removal of contamination or foreign objects such as dirt or debris.

Additionally, the powerful yet safe iodine-copper technology of Bioclynse WIS releases a controlled amount of free iodine (about 250 ppm) and copper ions, which together produce a synergistic effect to cleanse,

irrigate, and debride wounds. This helps to avoid complications caused by biofilms or microbial infection.

Free iodine acts as a powerful broad-spectrum antimicrobial preservative agent that inhibits contamination within the solution for effective wound cleaning. It is not intended to provide therapeutic benefits.

# Efficacy

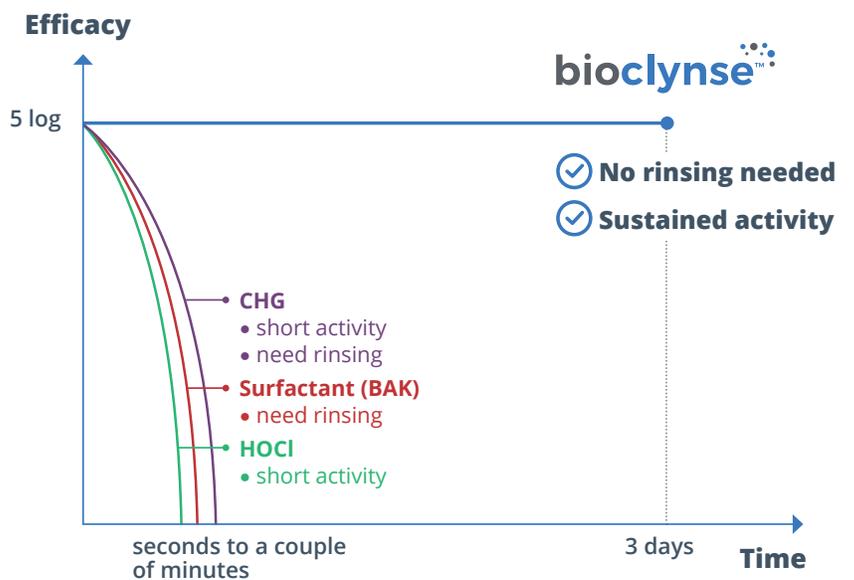
✓ **Bioclynsse: >99.999% effectiveness (5 log reduction)** <sup>2,3</sup>

✓ **Sustained Activity up to 3 days against**

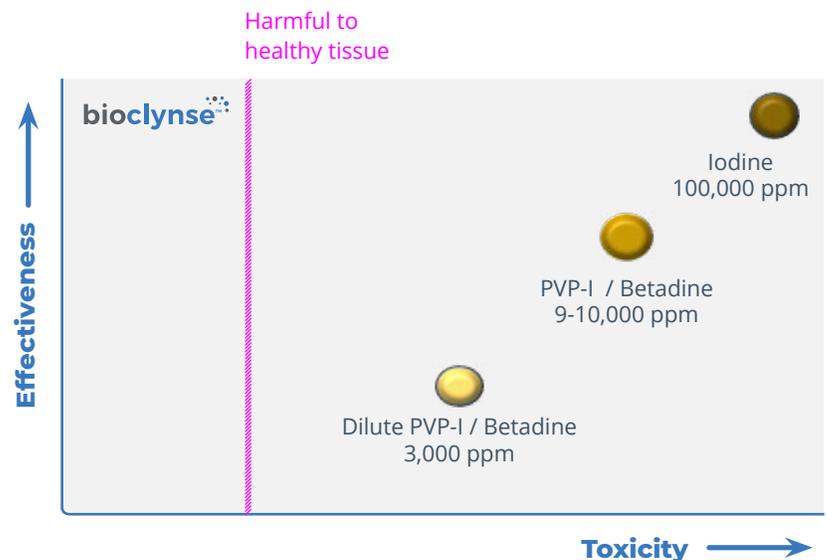
- *Enterococcus faecium*
  - *Staphylococcus aureus*
  - *Klebsiella pneumoniae*
  - *Acinetobacter baumannii*
  - *Pseudomonas aeruginosa*
- *Enterobacter aerogenes*
  - *Bacteroides fragilis*
  - *Escherichia coli*
  - *Candida albicans*
  - *Aspergillus brasiliensis*



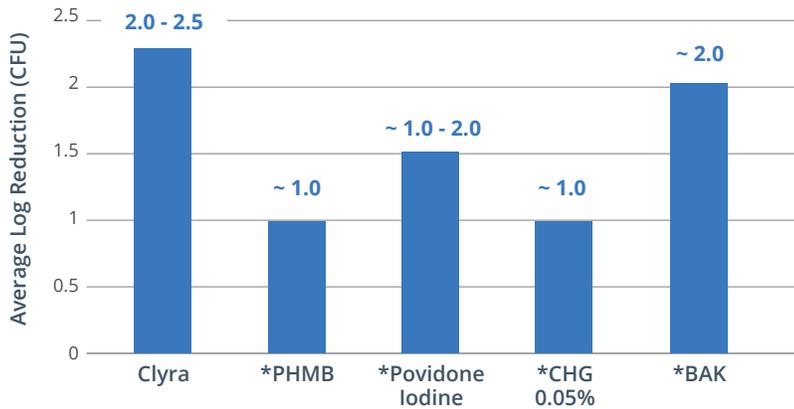
## Competitive performance



## Iodine Efficacy vs Toxicity



## BioclyNSE use on mature biofilm with 2.0 - 2.5 log reduction



\*Retrospective Data Collection and Analysis

### Clyra Biofilm Study<sup>1</sup>

Pig study with 1.5 cm wounds inoculated to create mature biofilm  
Biofilm species: *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Fusobacterium* biopsied 24 hours later.

## BioclyNSE label

bioclyNSE™

### WOUND IRRIGATION SOLUTION

- Professional use only
- Debridement irrigation
- Disruption of biofilm
- Removal of microorganisms

THE CLYRADVANTAGE™

32 fl oz (946 mL)  
Rx Only

#### INDICATIONS FOR USE:

BioclyNSE Wound Irrigation Solution is intended for use by healthcare professionals for cleansing, irrigating, moistening and debriding to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wounds such as 1st and 2nd degree burns, stage I-IV pressure ulcers, diabetic ulcers, stasis ulcers, abrasions and minor skin irritations, post-surgical wounds, grafted and donor sites, in addition to moistening and lubricating absorbent wound dressings.

BioclyNSE Wound Irrigation Solution is a clear solution based on a copper - iodine complex platform that is topically applied to wound areas. The resulting iodine is in a concentration within the product at approximately 250 parts per million (ppm). Iodine acts as a preservative to inhibit growth of microorganisms within the solution.

#### DIRECTIONS FOR USE:

BioclyNSE Wound Irrigation Solution may be used with a vented spike irrigation set prior to hanging for application. BioclyNSE Wound Irrigation Solution is compatible with pulse lavage, ultrasonic debridement and negative pressure wound therapy. For single use only.

**Caution:** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

**Warning:** For external use only. Not for injection, IV or ophthalmic use. Do not use if there is a history of allergy to any of the ingredients. The product is contraindicated for use in patients with Wilson's disease.

**Handling:** Non-irritating, non-toxic, and non-sensitizing. No special handling precautions required.

**Storage Conditions:** Store at 15 - 30°C. Avoid excessive heat.

**Disposal:** Dispose of the bottle and solution after expiration date. No special disposal considerations are required.

**Further Information:** For additional information or reporting of adverse events please contact customer service at the address below.

MADE IN THE USA  
Manufactured in the US for  
Clyra Medical Technologies Inc.  
14921 Chestnut St  
Westminster, CA, 92683  
(239) 206-1213

BWISB32BRRev02

REF: CMBC-001L



750 mL

24 oz

500 mL

16 oz

250 mL

8 oz

## References

- GLP Pig study to assess the anti-biofilm and antimicrobial activity. BRIDGE PTS. Study Number: GLP-170217. 2017.
- GLP Time Kill Study. Nelson Laboratories. Study Numbers: 913680-S01 (Bacteria) and 1012993-S01 (Fungus). 2016-2018.
- Antimicrobial Effectiveness Test (AET) (USP<51>). KLM Labs.
- GLP Direct Primary Skin Irritation Test - Abraded Method (ISO 10993-10). Nelson Laboratories. Report: 19-00374-G1. Report Number: NL# 1144568. 2019.
- GLP Guinea Pig Maximization Sensitization Test (ISO 10993-10). Nelson Laboratories. Test code: 900854.1. Report Number: 122860. 2018.
- GLP Materials Mediated Rabbit Pyrogen (No Extraction). Nelson Laboratories. Test code: 900770.3. Report Number: 118088. 2018.
- GLP Cytotoxicity by Agar Overlay (ISO 10993-5). Nelson Laboratories. Report number: 1012989-S01. 2018.