ViaCLYR™
WITH CLYRASEPT™

Antimicrobial Effectiveness: Technical Summary

In Vitro Time-Kill Study | Copper-Iodine Complex Solution (CICS)

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1. Product Overview

ViaCLYR is an FDA 510(k)-cleared wound management solution based on Copper-Iodine Complex Solution (CICS) — a patented, pH-balanced antimicrobial formulated from copper sulfate and potassium iodide in a balanced sodium chloride solution. Its native pH of 5.0 is consistent with normal dermal pH, inhibiting microbial pathogen survival and biofilm development.

ViaCLYR is indicated for wound management, cleansing, irrigation, moisturization, and debridement of acute and chronic dermal lesions, including partial and full thickness wounds. Approved indications include 1st and 2nd degree burns, Stage I–IV pressure ulcers, diabetic and stasis ulcers, post-surgical wounds, abrasions, and minor skin irritations.

Key Scientific Properties

- ✓ Non-cytotoxic, non-pyrogenic, non-irritating, and non-sensitizing to dermal tissue — no rinse required after application
- ✓ Broad-spectrum effectiveness against bacteria (including MRSA and VRE), yeast, fungi, and viruses
- ✓ No known antimicrobial resistance — CICS does not promote the development of resistant microorganisms
- ✓ Compatible with static or pulsed lavage, low-frequency ultrasonic, and hydrosurgical debridement
- ✓ 24-month shelf life; stable across a broad temperature range (0°C to 55°C)

2. Mechanism of Action

ViaCLYR is an FDA 510(k) cleared medical device and has a dual mechanism of action. CICS is antimicrobial in solution as a preservative and neutralizes pathologic microorganisms. Through the mechanical and physical movement of the solution across the wound bed, the neutralized microorganisms, dirt and debris are effectively rinsed away. All this is accomplished in a non-cytotoxic, non-irritating, non-sensitizing, and dermal pH balanced environment.

3. “Chemistry on Demand” — Sustained Effectiveness As It’s Needed

ViaCLYR contains a potential of some 250 ppm of iodine in solution. Through ViaCLYR’s unique equilibrium ‘chemistry’, this potential is transformed ‘on demand’ into free iodine in the small amounts needed to neutralize any microbial pathogens present, leaving a significant reserve of iodine that stands ready to address future contamination throughout the product’s use lifecycle.

Persistence was validated by introducing pathogen aliquots at 10 minutes, 4 hours, 24 hours, 48 hours, and 72 hours with no additional fresh CICS added at any point — demonstrating sustained antimicrobial effectiveness in the face of repeated microbial assaults across all time points.

4. In Vitro Time-Kill Results

The table below summarizes in vitro time-kill results for CICS against 19 pathogenic microorganisms, including drug-resistant strains MRSA, VRE, and Candida auris. All standard bacterial and fungal organisms achieved neutralization at 1 minute of exposure.

Microorganism	Time-Kill	Reduction (Percent)
Pseudomonas aeruginosa	1 min	99.9791%
Staphylococcus aureus	1 min	100%
Staphylococcus aureus (MRSA)	1 min	99.9979%
Staphylococcus epidermidis	1 min	100%
Streptococcus pyogenes	1 min	100%
Streptococcus salivarius	1 min	99.9998%
Enterococcus faecalis	1 min	99.0064%
Enterococcus faecium (VRE)	1 min	99.3426%
Enterococcus faecium	1 min	100%
Escherichia coli	1 min	100%
Klebsiella pneumoniae	1 min	100%
Klebsiella aerogenes	1 min	100%
Acinetobacter baumannii	1 min	100%
Proteus mirabilis	1 min	100%
Candida albicans	1 min	99.9251%
Candida tropicalis	1 min	96.8063%
Candida auris	1 min	96.6024%
Trichophyton interdigitale	1 min	100%
Cutibacterium acnes	1 min	99.9999%

In vitro testing conducted per ASTM E2315 methodology at 37°C (body temperature). Results expressed as percent reduction from initial inoculum concentration.

4a. Clostridium difficile (Endpores)

C. difficile endospores require extended contact time for significant reduction due to their protective structure, but CICS remains significantly potent and highly effective over time. The table below reflects CICS's progressive effectiveness against C. difficile endospores.

Exposure Time	Reduction (Percent)
30 minutes	67.2789%
1 hour	86.7129%
4 hours	96.4405%
24 hours	99.9992%

C. difficile endospore testing conducted per modified ASTM E2839-11 methodology, testing at 20°C.

5. Comparative Cytotoxicity

ViaCLYR was evaluated alongside standard wound care agents for cytotoxicity. Several commonly used irrigants have been shown in vitro to impair the cells involved in normal wound healing. ViaCLYR passed all cytotoxicity assessments, confirming it does not harm healthy dermal tissue.

Wound Irrigant	Cytotoxicity Result
Copper-Iodine Complex Solution (ViaCLYR)	**Pass**
Saline (0.9% NaCl)	**Pass**
Hypochlorous Acid (0.024%)	**Pass**
Sodium Hypochlorite — Dakin's (0.25%)	**Fail**
Sodium Hypochlorite — Dakin's (0.5%)	**Fail**
Chlorhexidine Gluconate (4%)	**Fail**
Hydrogen Peroxide (3%)	**Fail**
Povidone Iodine (7.5%)	**Fail**

Source: Innovacyn Technical Report ITR017-1. ISO 10993-5 cytotoxicity methodology. Pass = non-cytotoxic; Fail = demonstrated cytotoxic activity in vitro.

6. Temperature Stability & Storage

- 24-month shelf life under standard conditions
- Validated across a broad temperature range, supporting use in diverse clinical and field environments
- Cold-chain compatible 0°C (32°F)
- Optimized for physiologic conditions

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