



# Irrisept®

ANTIMICROBIAL WOUND LAVAGE



*An alternative to traditional irrigation*

Irrisept Antimicrobial Wound Lavage contains 0.05% CHG in 99.95% Sterile Water for Irrigation, USP.

## FEATURES

- ◆ Chlorhexidine Gluconate (CHG) provides broad spectrum activity against various bacteria, fungi, and viruses in the solution.<sup>1</sup>
- ◆ Self-contained and sterile packaged, Irrisept is ready to open and use. No special training required.
- ◆ Meets American College of Surgeons recommendations for low pressure irrigation.<sup>2</sup>
- ◆ CHG acts as a preservative to inhibit microbial growth in the solution.



Intended to mechanically cleanse and remove debris, dirt and foreign materials, including microorganisms from wounds.

*Irrisept is a Class II Medical Device and an unclassified combination product.*

[www.irrisept.com](http://www.irrisept.com)



## DEDICATION TO RESEARCH

We are committed to building clinical evidence to support the safety and effectiveness of our products.

## VALUE ADDED SERVICES

- Direct support from Medical Affairs Team
- Continuing Education (CE) courses
- Investigator Initiated Research program

## BIOCOMPATIBILITY STUDIES<sup>3</sup>

### Range of Tests completed:

- Cytotoxicity
- Sensitization/Immune Allergic Response
- Skin Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogens

## WARNINGS AND CAUTIONS

Do not use this product if the patient is allergic to chlorhexidine gluconate. Discontinue use immediately if irritation, sensitization or allergic reaction occurs. Do not use unless solution is clear and bottle twist seal is intact. When using this product, keep away from the eyes and ear canals. If the solution inadvertently contacts these areas, rinse out promptly and thoroughly with water and/or normal saline. Not for injection. Single patient use only. Irrisept is intended for use by healthcare professionals only. Irrisept solution meets biocompatibility guidelines for ≤ 24 hours contact with breached or compromised surfaces (ISO 10993-1). Do not use if package is damaged. Rx only. Non-pyrogenic. Not made with Natural rubber latex.

## REFERENCES

1. IRR121 KTK Summary
2. ACS Surgery 7\_Princ and Prac\_5 Acute Wound Care\_215.
3. Biocompatibility data on file at Irrimax Corporation and available upon request.
4. USP 51 Test Report Geneva Labs JN16L0112-B104.

## USP Antimicrobial Effectiveness test Meets USP <51> Category 2 Criteria<sup>4</sup>

ORGANISMS	DAY 14	DAY 28
<i>S. Aureus</i> (ATCC 6538) <i>E. Coli</i> (ATCC 8739) <i>P. Aeruginosa</i> (ATCC 9027)	Greater than 2.0 log reduction from initial counts.	No increase from 14 days counts.
<i>C. albicans</i> (ATCC 10231) <i>A. brasiliensis</i> (ATCC 16404)	No increase from initial calculated counts.	No increase from initial calculated counts.

Irrisept has been tested against a broad spectrum of organisms including gram positive and gram negative bacteria, virus and fungi per the Kinetic Time-Kill method, over a range of 1 minute to 30 minutes after exposure. CHG acts as a preservative to help inhibit microbial growth in the solution.

## Additional organisms tested<sup>1</sup> include

### BACTERIA

*Acinetobacter baumannii*  
*Bacteroides fragilis*  
*Cutibacterium acnes* (formerly *Propionibacterium acnes*)  
*Enterobacter cloacae* MDR  
*Enterococcus faecium* VRE  
*Escherichia coli*  
*Klebsiella pneumoniae*  
*Prevotella intermedia*  
*Pseudomonas aeruginosa*  
*Ralstonia pickettii*  
*Staphylococcus aureus* MRSA  
*Staphylococcus epidermidis*  
*Streptococcus pyogenes*

### FUNGI

*Aspergillus niger* van Tiegham  
*Candida albicans*  
*Candida auris*

### VIRUS

Hepatitis B Virus Surrogate  
Hepatitis C Virus Surrogate  
Human Immunodeficiency Virus Type 1 (HIV-1)



## ORDERING INFORMATION FOR IRRISEPT

REF #: ISEPT-450-USA (sold by the case/12 Irrisept units per case)

Irrisept Package contents: (1) 450 ml bottle of 0.05% CHG in 99.95% Sterile Water for Irrigation, USP  
(1) Irriprobe® applicator

Customer Service Phone: 770.807.8445 or Direct Email: [cs@irrisept.com](mailto:cs@irrisept.com)

Order IRRISEPT through most major US medical/surgical distributors.





**Product Information**

**Product Code: ISEPT-450-USA**

**Contents include:**

- (1) 450 mL bottle of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP)
- (1) Irriprobe<sup>®</sup> applicator

Irrisept Antimicrobial Wound Lavage is sterile packaged and aseptically-filled in a Blow-Fill-Seal (BFS) bottle. Contents are wrapped in two sequential Central Supply Room (CSR) wraps and sealed in a Tyvek<sup>®</sup> pouch. CHG acts as a preservative to inhibit microbial growth in the solution.

**Directions for use:**



Remove TYVEK<sup>®</sup> strip to open pouch. Recommend placing double-wrapped CSR on flat surface to open. Irrisept bottle and Irriprobe applicator are loose together inside second CSR wrap. *(Please remove and discard the clear protective sleeve, it is not a component of the device.)*



Grasp bottle top firmly and twist **quickly** in **ONLY ONE** direction, until seal cap snaps off.

Attach applicator to bottle.

Invert bottle. Using manual compression, direct stream into wound ensuring complete coverage.

Wait approximately one minute, rinse with normal saline for irrigation. Discard any unused solution.



## INDICATIONS FOR USE

Irrisept Antimicrobial Wound Lavage is intended for mechanical cleansing and removal of debris, dirt, and foreign materials, including microorganisms from wounds.

## WARNINGS

- Do not use this product if the patient is allergic to chlorhexidine gluconate.
- Discontinue use immediately if irritation, sensitization or allergic reaction occurs.

## CAUTIONS

- Do not use unless solution is clear and bottle twist seal is intact.
- When using this product, keep away from the eyes and ear canals. If the solution inadvertently contacts these areas, rinse out promptly and thoroughly with water and/or normal saline.
- Not for injection.
- Single patient use only.
- Irrisept is intended for use by healthcare professionals only. Irrisept solutions meets biocompatibility guidelines for  $\leq 24$  hours contact with breached or compromised surfaces (ISO 10993-1).
- Not made with natural rubber latex.
- Do not use if the package is damaged.
- Rx only.
- Non-pyrogenic.

Irrisept Antimicrobial Wound Lavage is a Class II Medical Device and an unclassified combination product.

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