



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.¹
- 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.²
- CHG acts as a preservative to inhibit microbial growth in the solution.



Featuring NEW
Convenience Cap

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



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 STUDIES³

Range of Tests completed:

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

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. See label for full product details.

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 Criteria⁴

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 tested¹ 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 IRISEPT

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

Order IRISEPT through most major US medical/surgical distributors.

