



DO YOUR BEST AGAINST THE WORST.

Add Irrisept
to your infection
prevention plan.



A self-contained, sterile-packaged jet lavage delivering low pressure irrigation to meet your clinical needs.

Harnessing the power of CHG as a preservative in the solution to offer broad spectrum activity against various microorganisms.

Irrisept is non-cytotoxic and backed by evidence.

www.irrisept.com

THE ROLE OF IRRIGATION IN INFECTION PREVENTION

Infection is the most common complication of a wound.¹ A wound infection with microorganisms is one of the most common HAIs, globally.²

By using wound irrigation, you can remove foreign materials, cellular debris, and bacterial contaminants from wounds.¹⁻² Microorganisms may be more susceptible to removal when a combination of mechanical action and a preservative (like CHG) in the solution are used.³⁻⁴ The choice of irrigation can be a critical component in your infection prevention plan.¹

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



WHAT IS CHG?

Chlorhexidine Gluconate, or **CHG**, is a well-known antimicrobial used in pharmaceuticals and medical devices for more than half a century.^{5, 7} CHG is a positively (+) charged molecule that rapidly binds to a negatively (-) charged bacterial cell wall, causing disruption of the cell membrane and subsequent cellular death.^{5, 7}



As a preservative in the solution, CHG features:

- Broad spectrum activity against a variety of gram-positive and gram-negative bacteria, fungi, and some viruses.^{5, 8}
- Quick onset of action/persistent effect, allowing it to remain active long after the initial application.^{5, 7-9}
- Antimicrobial activity not limited by the presence of body fluids such as blood, in contrast to povidone-iodine.⁹⁻¹⁰

Irrisept offers Performance, Safety, and Ease of Use and is backed by testing and independent research.^{5,8,10-15,17-24}



- CHG preservative effective against gram-positive and gram-negative bacteria, fungi, and some viruses^{5, 8}
- Outperforms 0.35% PVP-I in inhibiting the growth of microorganisms in the presence of organic matter¹⁰
- Biofilm disruption >99% on tested organisms in CDC Biofilm Reactor Study¹¹

- Extensive safety testing including in-vivo studies and RCT data^{13, 15}
- For all types of wounds
- Non-cytotoxic¹³

- Sterile-packaged, ready to open and use
- Manual compression, delivers low pressure irrigation per ACS recommendations¹²
- Requires no mixing or dilution, dispensing, or attachment to other irrigation systems
- Referenced by name and/or concentration in independent publications¹⁷⁻²⁴



TRUSTED BY MORE THAN
3,000
U.S. HOSPITALS FOR THEIR
IRRIGATION NEEDS¹⁴

IRRISEPT – IRRIGATION WITH EVIDENCE

*all studies are available upon request

CDC Biofilm Reactor Study¹¹

Irrisept mechanically disrupted all clinically relevant biofilms tested.

>99% reduction

Figure 1:
SEM of
P. aeruginosa
(ATCC®
15442™)
on titanium
coupons

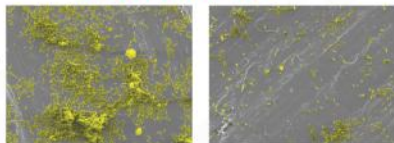


Image Left: Growth control; Image Right: Biofilm after treatment with Irrisept per IFU.

Figure 2:
SEM of
E. coli
(ATCC®
25922™)
on titanium
coupons

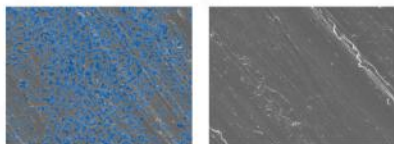
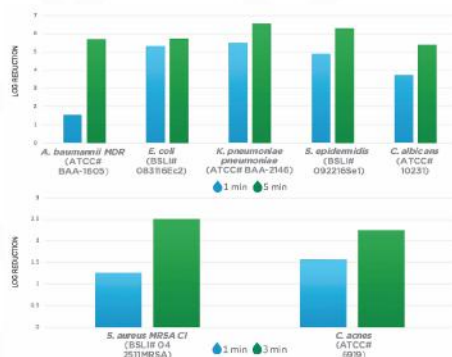


Image Left: Growth control; Image Right: Biofilm after treatment with Irrisept per IFU.

Kinetic Time-Kill Study⁸

Shows Irrisept was effective in reducing the microbial load against a variety of gram-positive and gram-negative bacteria, fungi, and viruses in the solution.

*Refer to study for full list of organisms tested.



IRRISEPT VS 0.35% PVP-I¹⁰

Determination of the MIC & MBC in the presence of organic matter shows superior results with Irrisept.

- MIC Assay: No visible growth observed for 0.05% CHG with or without the presence of organic matter whereas microbial growth was observed on all organisms tested for 0.35% PVP-I in the presence of organic matter.
- MBC Assay: Microbial count reduction was $>4.24 \log_{10}$ with 0.05% CHG for all tested organisms with or without presence of organic matter whereas microbial count reduction with 0.35% PVP-I was $<2.15 \log_{10}$ for all organisms tested in the presence of organic matter.

MBC ASSAY RESULTS

Test Article	Microbial Reduction									
	<i>E. coli</i>		<i>P. aeruginosa</i>		<i>S. aureus</i>		<i>S. epidermidis</i>		<i>S. agalactiae</i>	
	%	Log ₁₀	%	Log ₁₀	%	Log ₁₀	%	Log ₁₀	%	Log ₁₀
0.05% CHG	99.99	4.24	99.99	4.31	99.99	4.55	99.99	4.49	99.99	4.45
0.05% CHG + 10% serum	99.99	4.24	99.99	4.31	99.99	4.55	99.99	4.49	99.99	4.45
0.35 PVP-I	≤98.55	1.84	≤98.77	1.91	99.99	4.55	99.99	4.49	99.99	4.45
0.35 PVP-I + 10% serum	≤98.55	1.84	≤98.77	1.91	≤99.30	2.15	≤99.20	2.09	≤99.11	2.05

Extensive safety studies, including in-vivo testing and RCT data^{13, 15}

Study Description	Pass/Complete	Results/Conclusion
Cytotoxicity	✓	Irrisept solution is non-cytotoxic. No abnormal events such as pH change or debris were noted.
Skin Irritation	✓	Irrisept solution did not elicit any kind of sensitization response.
Immune Allergic Response	✓	Irrisept solution passed ISO Intracutaneous Reactivity Test.

List of other in-vivo safety studies

- Hemolysis
- Pharmacokinetics
- Intraperitoneal Organ Toxicity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Neurotoxicity
- Thoracic Tissue Toxicity – Porcine
- Thoracic Adhesion Study – Canine
- Intra-Articular Cell Toxicity
- Wound Healing Study
- CLP-01 (Assessment of RCT: Irrisept vs SOC)¹⁵

IRRISEPT IS DESIGNED WITH EASE OF USE IN MIND



Irrisept is sterile-packaged, ready to open and use



Simply open the bottle and attach the Irriprobe® applicator



Manually compress the bottle to deliver stream directly to the site

No mixing, dispensing, diluting, or attachment to additional irrigation devices necessary

WHEN COMPARED TO IRRISEPT, HOW DO OTHER IRRIGATIONS MEASURE UP?

Check and compare using the table below

Irrigation Profiles	Irrisept	Other Solution (Normal Saline, Antibiotics, PVP-I, Other)
Demonstrates effectiveness as a preservative against gram-positive and gram-negative bacteria, fungi, and viruses in the solution ^{5,8}	✓	
Requires no mixing or dilution, dispensing, or attachment to other irrigation systems, unless desired	✓	
Features extensive safety studies, including in-vivo testing and RCT results ^{13, 15}	✓	
Sterile packaged and ready to use	✓	
For use on all types of wounds	✓	
Delivers low pressure irrigation per American College of Surgeons' recommendations ¹²	✓	
Aligns with the goals of Antibiotic Stewardship Programs ¹⁶	✓	
Does not impede wound healing properties ¹³	✓	
Referenced by name and/or concentration in independent publications ¹⁷⁻²⁴	✓	
Free of surfactants, excipients, detergents, and other solvents	✓	
Non-pyrogenic	✓	
Healthcare economic data available upon request	✓	
<\$80/use	✓	



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 in adults 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 the package is damaged.
- Rx only.

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ORDERING INFORMATION:

REF#	PRODUCT NAME	PRODUCT DESCRIPTION	CASE QTY
ISEPT-450-USA	Irrisept Antimicrobial Wound Lavage	450mL bottle of Irrisept Antimicrobial Wound Lavage, with Irriprobe	12
ISEPT-150-USA	Irrisept Antimicrobial Wound Lavage	150mL bottle of Irrisept Antimicrobial Wound Lavage, with Irriprobe	15

Irrisept Antimicrobial Wound Lavage is available through most medical supply distributors. To order Irrisept, contact your preferred distributor, your Irrisept Sales Representative, or Irrisept Customer Service.

