

FINALLY, AN ALTERNATIVE TO SALINE IRRIGATION

IRRISEPT® O.R.

0.05% Chlorhexidine Gluconate (CHG) in Water for Irrigation, USP
An FDA-Cleared Cleansing and Debridement System

SURGICAL SITE INFECTIONS (SSIs) - A MAJOR PROBLEM*:

(Compared to uninfected surgical patients)

- ▶ MRSA SSIs cost a hospital >\$60,000 per occurrence
- ▶ MRSA SSIs lead to 16 days of additional hospitalization
- ▶ Patients with MRSA SSIs have >5x increased mortality rates



IrriSept® O.R.
with IrriProbe®

EXAMPLES OF IRRISEPT O.R. USE INCLUDE:

- ▶ Surgical Procedures (as a final rinse before closure)
 - Orthopedic Surgery
 - General Surgery
 - Plastic & Reconstructive Surgery
 - Cardiothoracic Surgery
 - Neurologic Surgery
- ▶ Surgical Site Infections (SSI)
- ▶ Skin & Soft Tissue Infections (SSTI)
- ▶ Delayed Closure
- ▶ Abscesses
- ▶ Deep Traumatic Wounds
- ▶ Wound Dehiscence
- ▶ Pilonidal cysts
- ▶ Burns

IrriSept is indicated for use on wounds.

Contraindicated for patients with CHG Allergy. Keep away from eyes and ear canals; if there is contact with these areas, rinse out promptly and thoroughly with water or normal saline.

OUR COMPANY GOALS:

- ▶ Help Treat and Prevent Infections, including HAIs and SSIs
- ▶ Help Improve Patient Outcomes
- ▶ Help Increase the Safety of Health Care Professionals

THE IRRISEPT O.R. ADVANTAGE (0.05% CHG):

- ▶ **Effective** – Shown effective in laboratory testing against a variety of bacteria and fungi, including MRSA and Pseudomonas^{1,2}
- ▶ **Fast Acting** – In log-reduction studies, exposure to IrriSept solution resulted in >99.8% reduction at one minute for MRSA and Pseudomonas⁶
- ▶ **Persistent** – Destroyed and inhibited MRSA and Coag-neg Staph growth on lab samples for 14 days²
- ▶ **FDA-Cleared** – The only FDA-cleared cleansing and debridement system with CHG
- ▶ **Safe** – Passed the FDA required tests for cytotoxicity, skin irritation, and immune (allergic) response³
- ▶ **Versatile** – Features a series of three unique applicators, designed to help cleanse and debride wounds

For orders, samples, and clinical information, visit www.IrriSept.com or call 770-807-8445

IRRISEPT O.R. - DEMONSTRATED RESULTS:

LOG REDUCTION STUDY⁶

Irrisept solution was evaluated in lab testing for effectiveness against MRSA and Pseudomonas at 3 time intervals.

IRRISEPT REDUCTION OF MICROORGANISMS FROM BASELINE

| Time | MRSA | | Pseudomonas aeruginosa | |
|--------------|---------------|-------------|------------------------|-------------|
| | Log Reduction | % Reduction | Log Reduction | % Reduction |
| One minute | 2.83 | 99.8% | >6.74 | >99.9% |
| Five minutes | 5.70 | 99.9% | >6.74 | >99.9% |
| 24 hours | 5.81 | > 99.9% | >6.74 | >99.9% |

MRSA IMPLANTATION STUDY⁵

Surgical hernias were created and covered with mesh in 16 rats. The mesh was inoculated with MRSA. Prior to closure, 50% were irrigated with Irrisept and 50% with saline (usual practice). All rats were tested for infection at 7 days.

Clinical Outcomes:

- ▶ 0% MRSA clinical infection rate in rats irrigated with Irrisept
- ▶ 100% MRSA clinical infection rate in rats irrigated with saline

IRRISEPT O.R. IS EASY TO USE:

STEP 1
CLEANSE AND DEBRIDE WITH IRRISEPT O.R.




WAIT 1 MINUTE

STEP 2
RINSE WITH IRRISEPT O.R.

HOW IT WORKS:

Through bottle compression, the patented Irrisept O.R. system delivers 450mL of solution in less than 30 seconds to effectively loosen and remove wound debris and bacteria without harming underlying tissues.

IRRIGATION APPLICATORS:

| | | |
|---|--|--|
| <p>SplatterGuard[®]</p> <p>The SplatterGuard facilitates splatter protection and decreases aerosolized contamination during wound cleansing and debridement procedures.</p>  | <p>LT SplatterGuard[®]</p> <p>The LT SplatterGuard facilitates splatter protection and decreases aerosolized contamination during wound cleansing and debridement of abscesses.</p>  | <p>IrriProbe[®]</p> <p>The IrriProbe facilitates deep tissue wound cleansing and debridement in an operating room setting.</p>  |
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ORDER INFORMATION:

Each Irrisept O.R. system contains:

- (1) Irrisept O.R. – 450 mL bottle with 0.05% Chlorhexidine Gluconate (CHG) in water for irrigation, USP (99.95%)
- (1) Irririnse O.R. – 450 mL bottle with 0.9% Sodium Chloride, USP
- (1) SplatterGuard
- (1) LT SplatterGuard
- (1) IrriProbe

Catalog #: Irrisept 403
Order Unit: Case / 6 eaches



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IRRI MAX CORPORATION

Irrimax Corporation develops wound solutions that incorporate an innovative delivery method to obtain unmatched efficacy and safety. Irrimax's goal is to treat and prevent infection, improve patient outcomes and increase the safety of medical staff. Continual innovation and ongoing clinical research guide the development of Irrimax products.

U.S. Patent No. 5,830,197; 6,468,253; 7,662,125; 7,959,617; D588,692; and D556,595. Additional U.S. and Foreign Patents Pending.

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¹Laboratory Testing Records per USP <51>, Antimicrobial Effectiveness Testing, on file at IRRIMAX Corporation. ²Laboratory Testing Records, "Chlorhexidine Gluconate (CHG) Bacterial Study Report", on file at Irrimax Corporation. ³Biocompatibility compliance tests completed per FDA's Blue Book Memorandum G95-1 and ISO 10993-1, Biological Evaluation of Medical Devices, on file at IRRIMAX Corporation. ⁴Anderson, DJ et al, "Clinical and Financial Outcomes Due to Methicillin Resistant Staphylococcus aureus Surgical Site Infection: A Multi-Center Matched Outcomes Study", PLoS One, Dec. 2009. ⁵Study to Evaluate the Anti-Bacterial Efficacy of a Surgical Irrigant in a Rat Hernia Repair Infection Model. Unpublished laboratory report. (2009, November 6). WuXi AppTec, Inc., St. Paul, MN. Laboratory Testing Records. ⁶Time Kill Study GLP Report", on file at Irrimax Corporation.