Jet lavage containing low concentration Chlorhexidine Gluconate (CHG) 0.05% in sterile water for irrigation. CHG acts as a preservative to help inhibit microbial growth in the solution.

**Wound Lavage**

Irrisept’s bottle design allows users to control the pressure of the solution through manual bottle compression.

**IRRISEPT CONTENTS INCLUDE:**

(1) Irrisept, 450 mL bottle 0.05% Chlorhexidine Gluconate (CHG) in sterile water for irrigation USP (99.95%)
(1) Irriprobe® applicator

*Irrisept is cleared as a Class II Medical Device and an unclassified combination product (K080779).*

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 Grant program

Irrisept Wound Debridement & Cleansing System
The mechanical action of Irrisept effectively loosens particulate and debris from wounds.

PROVEN SAFE

Range of Tests completed:
- Cytotoxicity
- Sensitization/Immune Allergic Response
- Skin Irritation

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 eyes and ear canals. If the solution should contact these areas, rinse out promptly and thoroughly with water and/or normal saline. Federal law restricts this device to sale by or on the order of a licensed physician. Not for injection. Do not re-use. Do not use if the packaging is damaged or broken. Single patient use only.

REFERENCES
4. USP <51> Antimicrobial Effectiveness Test. Geneva Labs #JN16L0112-B104.*

* Data on file, Irrimax Corporation

USP Antimicrobial Effectiveness test Meets USP <51> Category 2 Criteria

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

Irrisept has been tested against a broad spectrum of organisms including gram positive and 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 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
- Aspergillus niger van Tiegham
- Candida albicans
- Candida auris
- Hepatitis B Virus Surrogate
- Hepatitis C Virus Surrogate
- Human Immunodeficiency Virus Type 1 (HIV-1)

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 eyes and ear canals. If the solution should contact these areas, rinse out promptly and thoroughly with water and/or normal saline. Federal law restricts this device to sale by or on the order of a licensed physician. Not for injection. Do not re-use. Do not use if the packaging is damaged or broken. Single patient use only.

ORDERING INFORMATION FOR IRRISEPT:

REF #: ISEPT-450-USA (sold by the case/12 Irrisept units per case)
Contact Customer Service direct: 770.807.8445 or via email cs@irrisept.com

PLEASE NOTE: Irrisept can only be sampled by a licensed healthcare provider

IRRISEPT is available to order through all major US medical/surgical distributors.

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IRR033 Irrisept Sales Sheet REV 07
All products manufactured in the USA.