

**REF** ISEPT-450-USA

FREQUENTLY ASKED QUESTIONS

1. What is Irrisept[®]?

Irrisept[®] Antimicrobial Wound Lavage is a single-use, manual, self-contained irrigation device comprised of (1) 450mL bottle of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP) and (1) applicator (Irriprobe[®]). The solution is aseptically-filled in a Blow-Fill-Seal (BFS) bottle. The CHG acts as a preservative to inhibit microbial growth in the solution.

Irrisept is a Class II Medical Device and an unclassified Combination Product.

REF # ISEPT-450-USA is packaged 12 single units to a case. Each unit is wrapped in two Central Supply Room (CSR) wraps and sealed in a Tyvek[®] pouch.

2. What are Irrisept's Indications For Use in the USA?

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

3. How does the device create pressure for irrigation?

Irrisept's bottle design allows users to control the delivery pressure of the solution through manual bottle compression. Grasping the bottle firmly, the user can control the direction and pressure desired to effectively loosen and remove wound debris.

4. Where can I use Irrisept?

Irrisept can be used for all types of wounds.

5. Is Irrisept safe to use on wounds?

Irrisept meets biocompatibility guidelines for ≤ 24 hours contact with breached or compromised surfaces following the ISO standard 10993-1. The following testing supports biocompatibility of Irrisept for the intended use of wound cleansing and debridement¹⁻¹¹:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogens

6. What are the risks and safety information associated with use of ISEPT-450-USA?

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 eyes and ear canals. If 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).
- Not made with natural rubber latex.
- Do not use if the package is damaged.
- Rx Only.

7. Is Irrisept sterile?

The solution is aseptically filled in a Blow-Fill-Seal (BFS) bottle. The bottle and applicator are EO-sterilized.

8. Why does Irrisept packaging state "Rx Only."?

Irrisept is a prescription device. FDA regulations require that prescription devices have the following statement "Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner." This caution statement is shown on the Irrisept product back pouch label to define the symbol Rx Only, which is shown on the front pouch label. Irrisept is not available over-the-counter or off-the-shelf through retail vendors.

9. Do I have to rinse with saline?

Labeling on ISEPT-450-USA states: 'Wait for approximately one minute, rinse with normal saline for irrigation. Discard any unused solution.'

10. Can Irrisept be used on more than one patient?

Labeling on ISEPT-450-USA states 'Single patient use only' along with 'single use only, do not reuse' symbol.

11. What are the storage condition requirements for Irrisept?

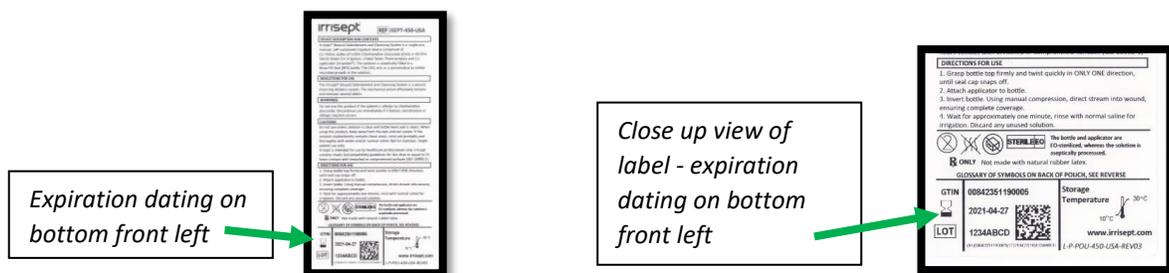
Labeling on ISEPT-450-USA states Storage Temperature is between 10°- 30° degrees Celsius (50°- 86° Fahrenheit).

12. What is the shelf life of Irrisept?

Irrisept maintains a 2-year shelf life from the date of manufacture, which is indicated on the pouch label.

13. Where can I find the expiration date on the Irrisept product?

The expiration date is located at the bottom of the ISEPT-450-USA pouch label.



14. Can Irrisept be warmed?

Irrisept may be warmed up to 40 °C (104 °F) and should not exceed 7 days before removal from the temperature-controlled warming cabinet.¹² Once removed, Irrisept should be used within 24 hours or discarded.

15. What is the pH range for Irrisept?

Each LOT of Irrisept is tested to meet a pH range of 5.0 to 7.0.

16. What is CHG?

CHG is Chlorhexidine Gluconate. It is a cationic bisbiguanide salt. CHG works by destroying the bacterial cell membrane and precipitating cell contents. The attraction of the positively charged CHG molecule to negatively charged bacterial cell wall causes disruption of the cell membrane and subsequent cellular death.¹³ CHG acts as a preservative to help inhibit microbial growth in the solution.

CUSTOMER SERVICE AND ORDERING INFORMATION

Customer Service - Please contact the customer service department directly, as needed.

PHONE	770-807-8445
EMAIL	cs@irrisept.com
FAX	770-807-8446

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

Sample product - Requests can be made through the IRRISEPT[®] website www.irrisept.com

**PLEASE NOTE: Irrisept is a "Rx Only" product and can only be sold to a licensed healthcare practitioner.*

Distribution - Irrisept is sold through national and regional medical/surgical distributors in the USA.

Reimbursement - There is currently no reimbursement code for Irrisept.

REFERENCES:

¹ISO 10993-5:2009 WuXi AppTec Cytotoxicity Assay for Liquids Using L-929 Mouse Fibroblast Cells. ² ISO 10993-5:2009 ISO MEM ELUTION ASSAY WITH L-929 MOUSE FIBROBLAST CELLS. ³ISO 10993-10: ISO Guinea Pig Maximization Sensitization Test for Liquid Articles. ⁴ISO 10993-10: ISO Guinea Pig Maximization Sensitization Test. ⁵ISO 10993-10: ISO Intracutaneous Irritation Test. ⁶ISO 10993-10: ISO Intracutaneous Irritation Test (GLP – 2 extracts) ⁷ ISO 10993-10: Irrisept Custom Irritation Study Report. ⁸ISO 10993-11 NAMSA GLP Study: Systemic Toxicity in Mice. ⁹ISO 10993-11: TR-16-025, Aging Study for the Irrisept 500–Version 2 Test Report. ¹⁰ ISO 10993-11: ISO Materials Mediated Rabbit Pyrogen (GLP). ¹¹ISO Acute Systemic Injection Test GLP-2 Extracts. ¹²TR 17-017 Irrisept Temperature Excursion Test Summary. ¹³McDonnell, G. and A.D. Russell, Antiseptics and disinfectants; activity, action and resistance. Clin Microbial Rev, 1999. 12(1): p.147-79.

