

FREQUENTLY ASKED QUESTIONS

This document applies to product code:

- ISEPT-150N-USA

Product Code	Contents	Unit of Measure
ISEPT-150N-USA	(1) 150 mL bottle of Irrisept (1) optional Spatterguard® accessory	15 units/case



Product and Use Information:

1. What is Irrisept®?

Irrisept® Antimicrobial Wound Lavage is a single-use, manual, self-contained device comprised of (1) bottle of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP) and (1) Splatterguard® accessory. The CHG acts as a preservative to inhibit microbial growth in the bottled solution. Irrisept is a Class II medical device and an unclassified combination product.

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

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:

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

Reports for all testing stated above, on file and available upon request through Irrimax Corporation.

6. What are the risks and safety information associated with the use of Irrisept Antimicrobial Wound Lavage?

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)

7. How is Irrisept packaged?

The Irrisept bottle, optional Splatterguard accessory, and printed IFU are packaged in an easy to store shelf carton. The bottle contains a solution that is manufactured using aseptic processing per ISO 13408 Aseptic Processing of Healthcare Products. The outside of the bottle, Splatterguard accessory and shelf carton packaging are non-sterile.

8. Why does Irrisept packaging state “Rx Only?”

Irrisept is a prescription device. The symbol “Rx Only,” is shown on the front of the shelf carton and IFU insert and is associated with the caution statement that FDA regulations require prescription devices to have, which states, “Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.” The Symbols Glossary for Irrisept products can be viewed on www.irrisept.qarad.eifu.online/IMX or by scanning the QR code on the front of the shelf carton or IFU insert. Irrisept is not available over the counter or off-the-shelf through retail vendors.

9. Do I have to rinse with saline?

Product labeling 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 all Irrisept products states ‘Single patient use only’ along with ‘single use only, do not reuse’ symbol.

11. What are the storage condition requirements for Irrisept?

Product labeling states storage temperature is between 10°- 30° degrees Celsius (50°- 86° Fahrenheit).²

12. What is the shelf life of Irrisept?

Irrisept maintains a 3-year shelf life from the date of manufacture, which is indicated on the shelf carton and shipping carton. Each individual shelf carton features a sticker with the expiration date, located at the top of the box. The shipping carton, which holds the 15 shelf cartons, also features a sticker with the expiration date.



13. Can Irrisept be warmed?

If desired, the Irrisept Antimicrobial Wound Lavage device may be warmed in its packaging up to 40°C (104°F) by placing it in a temperature-warming cabinet prior to use². Note: Prior to warming, store the device as per the device labeling.

14. What is the pH range for Irrisept?

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

15. 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.³ CHG acts as a preservative to help inhibit microbial growth in the bottled 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

Product Code	Contents	Unit of Measure
ISEPT-150N-USA	(1) 450 mL bottle of Irrisept (1) optional Splatterguard® accessory	15 units/case

Sample Product- Requests can be made online at www.irrisept.com

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

Reimbursement - There is currently no reimbursement code for Irrisept.

References:

1. Biocompatibility Matrix. Data on file at Irrimax Corp. Lawrenceville, GA
2. TR 17-017 Irrisept Temperature Excursion Test. Data on file at Irrimax Corp. Lawrenceville, GA
3. McDonnell, G. & Russell, A.D. (1999). Antiseptics and Disinfectants; Activity, Action and Resistance. Clin Micro Rev, 12(1), 147-179.
<https://doi.org/10.1128/cmr.12.1.147>