



FREQUENTLY ASKED QUESTIONS

1. What is Irrisept®?

Irrisept is jet lavage containing low concentration chlorhexidine gluconate (CHG) 0.05% in sterile water for irrigation. The mechanical action of the device effectively loosens particulate and debris. CHG acts as a preservative to help inhibit microbial growth in the solution.

Irrisept is cleared as a Class II Medical Device and an unclassified Combination Product in the USA (K080779).

Contents are wrapped in two sequential CSR wraps and sealed in Tyvek® pouch (Model # ISEPT-450-USA).

Irrisept contents include:

- (1) Irrisept (one 450 mL bottle containing 0.05% CHG in sterile water, USP (99.95%))
- (1) Irriprobe® applicator

2. How is Irrisept different from other 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 needed to effectively loosen and remove wound debris.

3. Where can I use Irrisept?

Irrisept can be used for open wounds of all types, including wounds post debridement.

4. Is Irrisept safe?

Irrisept has completed and passed safety testing according to the requirements of applicable ISO Standards.

Cytotoxicity¹

Sensitization/Immune Allergic Response²

Skin irritation³

5. What are Irrisept's warnings and/or cautions?

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 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 package is damaged or broken

Additional features: Not made with natural rubber latex. Single use, disposable. Self-contained, portable.

6. Why does Irrisept packaging state "Use as directed by a physician. Rx Only."?

Irrisept is cleared as a prescription device. FDA regulations require that prescription devices have the following statement "Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner." Irrimax Corporation uses the FDA accepted, abbreviated form of this statement on its labeling to conserve space: "Rx Only". Irrisept is not available over-the-counter or off-the-shelf through retail vendors.

7. Do I have to rinse with saline?

The directions for use state: Wait for approximately one minute, rinse with normal saline for irrigation.

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

Do not re-use. Single patient use only.

9. Can Irrisept be used in pediatrics?

Safety and effectiveness of Irrisept have not been studied in pediatric patients under the age of 18.

10. What are the storage condition requirements for Irrisept?

Irrisept is labeled for storage between 10°- 30° degrees Celsius (50°- 86° Fahrenheit).

11. 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.

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

The expiration date is located at the bottom of the pouch label, on the front of the product packaging.



13. Can Irrisept be warmed prior to use?

Irrisept may be warmed up to 40 °C (104 °F) and should not exceed 7 days before removal from the temperature-controlled warming cabinet.⁴ Once removed, Irrisept should be used within 24 hours or discarded.

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. Once the Irrisept bottle is opened, seal broken and removed, how long can the product be left open before it should be discarded?

Irrisept is intended for single use (i.e. used to irrigate a wound on a single patient).

16. Can Irrisept be used in conjunction with negative pressure wound therapy (NPWT)?

Wound cleansing and debridement is regularly performed prior to NPWT initiation or in conjunction with NPWT dressing changes. When using Irrisept in conjunction with NPWT, use per Irrisept instructions for use. Initiate NPWT as ordered and follow the NPWT manufacturer's directions.

17. 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.⁵ 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 sampled by 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

1. Biological Evaluation of Medical Devices, Part 5: Tests for In-Vitro Toxicity. Wuxi AppTec #187551 per ISO10993-5:2009.
2. Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization. Wuxi AppTec #187553 per ISO10993-10:2010.
3. Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization. Wuxi AppTec #1806 per ISO10993-10:2010.
4. IRRIMAX_20180306102052 ISEPT-500 Excursion Final Report JN171305.
5. McDonnell, G. and A.D. Russell, *Antiseptics and disinfectants: activity, action, and resistance*. Clin Microbiol Rev, 1999. 12(1): p. 147-79.

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