FREQUENTLY ASKED QUESTIONS

1. **What is Irrisept®?**
   Irrisept is a jet lavage system, containing low concentration chlorhexidine gluconate (CHG*) 0.05% in sterile water for irrigation.

   Irrisept is an FDA-cleared *(K080779)*, Class II Medical Device.

   Contents are wrapped in two sequential CSR wraps and sealed in Tyvek® header 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

   **CHG acts as a preservative to help inhibit microbial growth in the solution.*

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 help remove bacteria, debris and particulate.

3. **Where can I use Irrisept?**
   Irrisept is FDA-cleared for use on wounds. The mechanical action effectively loosens and removes wound debris.

4. **Is Irrisept safe?**
   Irrisept has successfully passed FDA safety testing[1] for:
   - Cytotoxicity
   - Skin irritation
   - Immune allergic response

   Ongoing testing is part of Irrisept's scientific program. Irrisept has subsequently conducted and successfully completed testing for:

   - Acute systemic toxicity
   - Neurotoxicity
   - Hemolysis
   - Pharmacokinetics
   - Thoracic Tissue Toxicity
   - Chondrocyte Toxicity
   - Intraperitoneal Tissue Toxicity

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

5. **Does Irrisept have any warnings and/or cautions?**
   Yes, they are as follows:
   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
- Single patient use only

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 only available to licensed healthcare professionals. FDA regulations require Irrisept packaging to state: "Federal law restricts this device to sales by or on the order of a license 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 stores or retail websites.

7. Do I have to rinse with saline?

Yes, the FDA-cleared labeling includes a rinse with normal saline for irrigation.

8. Can Irrisept be re-used?

Irrisept is designed as a single-use, disposable system.

9. Can Irrisept be used in children?

Irrimax Corporation does not have clearance for use in neonates or 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.

Full package view

Expiration dating on bottom front left

Close up view of expiration dating on package

Expiration dating on bottom front left

13. Can Irrisept be warmed prior to use?

Irrisept may be warmed up to 40 ^{0}C (104 ^{0}F) and should not exceed 7 days before removal from the temperature-controlled cabinet. Once removed, Irrisept should be used within 24 hours or discarded.

14. What is the pH range for Irrisept?

Irrisept is tested, as part of the manufacturing and quality requirements of Irrimax Corporation, to confirm that the solutions meet the pH requirements of USP. Each LOT of Irrisept meets a pH range of 5.0-7.0. Further details and testing data for all lots are on file at Irrimax Corporation.

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

Irrimax Corporation regularly performs contamination testing of sealed product. To date, contamination testing of open product in the field, with or without applicator in place, has not been conducted.

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. NPWT is not a debriding tool and is not a substitute for effective forms of debridement.[6] 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 cationic CHG molecule to negatively charged bacterial cells results in a rapid rate of bacterial cell death.[4] CHG acts as a preservative to help inhibit microbial growth in the solution.

18. Can CHG be used on burns?

CHG has been used in the management of burns.[5,7] The World Health Organization (WHO) recommends cleansing burns with CHG after debridement for burn management.[8]

19. Can I mix my own CHG solution?

Irrisept is a FDA-cleared product (K080779). Manufactured in an FDA-registered facility, in accordance with Good Manufacturing Practice (GMP) regulations, Irrisept is aseptically filled and manufactured to precise specifications. Irrimax Corporation holds the rights to US and worldwide patents that provide broad protection for the use of CHG concentrations of less than 1%. For more information, please contact the Irrisept Clinical Team.

CUSTOMER SERVICE AND ORDERING

20. How do I obtain a sample of Irrisept*?

Requesting a sample is easy.

- Call Cambridge Medical Co. at: 908.274.1974 or
- Email directly to your local account representative: support@cambridgemedco.com

21. *PLEASE NOTE: Irrisept is a "Rx Only" product and can only be sampled by a licensed healthcare practitioner.*

21. How is Irrisept packaged?

Irrisept contents are wrapped in two sequential CSR wraps and sealed in Tyvek® header pouch. Contents include (1) bottle of Irrisept (450mL, 0.05% CHG in sterile water, USP (99.95%)) and (1) Irriprobe applicator.

22. How do I order Irrisept?

We have contracted with National, US distributors and Group Purchasing Organizations, in addition to smaller regional distributors, to make ordering Irrisept easily accessible.

- Contact our Customer Service department directly at 770.807.8445 or email cs@irrisept.com to help identify the smoothest path to facilitating your order.
- Or – contact your local National Distributor and see if their local warehouse is already stocking the product in your area and order through your regular process.
- You can also reach out to your Irrisept Sales Representative for assistance in placing your initial order or helping you work with your preferred distributor to get started.

23. Which distributors handle Irrisept?

Irrisept can be ordered through these distributors:

- Cardinal
- Owens & Minor
- Medline
- McKesson
- Mohawk
- Henry Schein
- AmerisourceBergen
- Geo-Med *(SDVOSB/FSS/ECAT)*

References

1. Biocompatibility compliance tests completed per FDA's Blue Book Memorandum G95-1 and ISO 10093-1, Biological Evaluation of Medical Devices, on file at Irrimax Corporation.
2. Study: Systemic Toxicity in Mice; GLP Study Number T0626_504. NAMSA. Report on file at Irrimax Corporation.
3. Study: Neurological Toxicology with local effects after implantation assessment of Irrisept in a chronic rabbit dorsal; GLP Study number 265-01. NAMSA. Report on file at Irrimax Corporation.
4. CDC MMWR (2002). *Guideline for hand hygiene in health-care settings: Recommendations of the healthcare infection control practices advisory committee and the HICPAC/SHEA/APIC/IDSA hand hygiene task force.* 51:RR-16.
5. Denton, G. (2001). Chlorhexidine. In: Block, S. ed. *Disinfection, sterilization, and preservation.* 5th ed. Lippincott Williams & Wilkins; Philadelphia, PA. 321-336.
6. V.A.C. therapy: Clinical guidelines a reference source for clinicians (2012). Retrieved 9/11/2013 from http://www.kci1.com/cs/Satellite?blobcol=urldata&blobheadername1=Content-type&blobheadername2=Content-disposition&blobheadername3=MDT Type&blobheadervalue1=application%2Fpdf&blobheadervalue2=inline%3B+filename%3D913%252F210%252F2-B-128f_Clinical%2BGuidelines-WEB.pdf&blobheadervalue3=abinary%3B+charset%3DUTF-8&blobkey=id&blobtable=MungoBlobs&blobwhere=1226674964720&ssbinary=true)
7. WHO (2007). *Management of burns.* Retrieved from http://www.who.int/surgery/pubilcations/Burns management.pdf
8. Platt, J. & Bucknall, R.A. (1984). *An experimental evaluation of antiseptic wound irrigation. Journal of Hospital Infection.* 5:181-188.