



FREQUENTLY ASKED QUESTIONS

1. What is the Irrisept system?

Irrisept is a patented jet lavage system, containing low concentration chlorhexidine gluconate (CHG)* 0.05% in sterile water for irrigation, to clean a wound.

It is a FDA cleared Class II medical device.

The Irrisept system contents include:

- Step 1: Irrisept, 450mL bottle, 0.05% CHG in sterile water, USP- 99.95%
- Step 2: Irririnse, 450mL bottle, 0.9% sodium chloride (*sterile normal saline*), USP
- Three applicator tips designed for use with all Irrisept and Irririnse bottles.

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

2. How is using the Irrisept system 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 system?

Irrisept is cleared for use on wounds.

4. Is the Irrisept system safe?

Irrisept has successfully passed initial FDA safety testing for cytotoxicity, skin irritation and immune allergic response.¹ Ongoing testing is part of Irrisept's scientific program. Irrisept has also conducted and successfully passed safety testing for acute systemic toxicity and neurological toxicity.^{2,3}

5. Does Irrisept have any warnings and/or cautions?

Irrisept is contraindicated for patients with a known CHG allergy. Keep away from eyes and ear canals. If there is contact with these areas, rinse out promptly and thoroughly with water or normal saline. Discontinue use immediately if irritation sensitization or allergic reaction occurs. Do not use unless solution is clear and twist seal is intact. Discard if evidence of freezing. Not for injection. Federal law prohibits this device to sale by or on the order of a licensed physician.

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

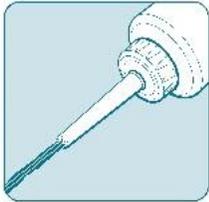
Irrisept is only available to licensed healthcare professionals. FDA regulations require Irrisept packaging to state: "Caution: Federal law restricts this device to sales by or on the order of a license healthcare practitioner." Irrimax Corporation uses the accepted, abbreviated form of this statement 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. Can Irrisept be used in children?

Irrimax Corporation does not have safety testing data or clinical trial data in neonatal or pediatric patients under the age of 18.

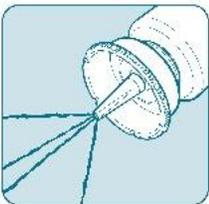
8. What applicators are available with the Irrisept system?

There are three custom-designed applicators available for use with the Irrisept system. All applicators fit both Irrisept and Irririnse bottles.



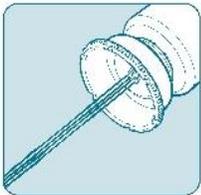
Irriprobe

The Irriprobe applicator is elongated with four parallel ports.



LT Splatterguard

The LT Splatterguard tip produces four multi-directional streams and helps decrease splash to the user and the environment.



Splatterguard

The Splatterguard produces four parallel streams and helps decrease splash to the user and the environment.

9. Do I have to use the rinse step?

Irrisept is manufactured as a two-step system and Instructions for Use includes a saline rinse step.

10. Can Irrisept be re-used?

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

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 expiration label on the packaging. Report TP-14-001 Summary is on file at Irrimax Corporation.

12. What are the storage condition requirements for the Irrisept system during warehousing and transportation?

Irrisept packaging, for warehousing and transportation purposes specifically, is labeled for storage between 10-30 degrees Celsius.

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

The expiration date label is located on the left side panel, of the Irrisept box/unit carton (see Images A, B and C below). That expiration date applies to the unit carton and its contents, that date supersedes any other expiration dates on the contents.



Image A (Unit Carton)

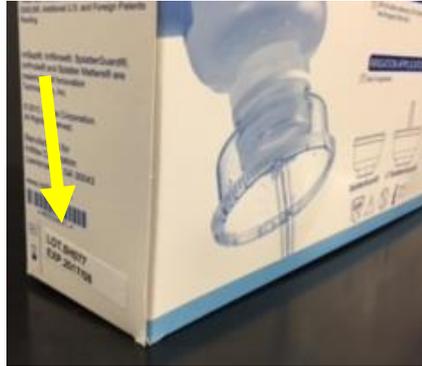


Image B (Unit Carton)

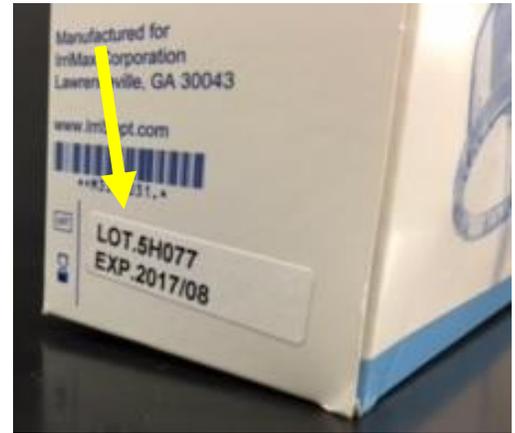


Image C (Unit Carton)

The Irrisept product maintains a 2-year shelf life, from the date of terminal sterilization. This is indicated as an expiration date on the unit carton label (as seen in Images above).

Please use the unit carton expiration date as the expiration date for entire product. Report TP-14-001 Summary is on file at Irrimax Corporation.

14. Why are there different expiration dates on the unit carton and the Irrisept and Irririnse bottles?

The contents of the unit carton (Irrisept bottle, Irririnse bottle and applicators) are manufactured separately, then packaged into the unit carton. Each bottle(s) and applicator(s) has its own, manufacturer expiration date(s).



Irrisept bottle

Examples of the expiration labeling on the Irrisept and Irririnse bottles.



Irririnse bottle

Once the bottles and applicators are packaged into the unit carton, the bottle(s) and applicator(s) individual expiration dates are superseded by the expiration date on the unit carton.

Please use the unit carton expiration date as the product expiration date.

15. 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 cabinet. Once removed, Irrisept should be used within 24 hours or discarded.

16. What is the pH range for Irrisept and Irririnse?

Irrisept and Irririnse are 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 and Irririnse meet a pH of 5.0-7.0. Further details and testing data for all lots are on file at Irrimax Corporation.

17. Once Irrisept and Irririnse bottles are opened, seals 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 applicators in place, has not been conducted.

18. 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 the Irrisept system in conjunction with NPWT, use Step 1 and Step 2 according to the Irrisept instructions for use. Initiate NPWT as ordered and follow the NPWT manufacturer's directions.

19. Can you explain the science of CHG?

CHG, a cationic bisbiguanide, 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

20. Can CHG be used for burns?

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

21. Can I mix my own CHG solution?

Irrisept is an FDA-cleared product, manufactured to precise specifications, with a critical percentage concentration of CHG in water, in an FDA-registered manufacturing facility in accordance with Good Manufacturing Practice (GMP) regulations. Irrimax Corporation holds the rights to US and worldwide patents that provide broad protection for the use of CHG concentrations of 1% or less. For further specifics regarding mixing CHG, please contact the Irrisept Clinical Team.

CUSTOMER SERVICE AND ORDERING

22. How do I obtain a sample of Irrisept?

Requesting a sample is easy.

- Visit our website www.irrisept.com and submit an online request
- Email directly to a Customer Service representative: cs@irrisept.com
- Call a Customer Service representative directly at [770.807.8445](tel:770.807.8445)

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

23. How is Irrisept packaged?

Irrisept is currently offered in sterile Tyvek tray packaging. The Irrisept system contents include Step 1 (Irrisept, 450mL, 0.05% CHG in sterile water, USP- 99.95%), Step 2 (Irririnse, 450mL, 0.9% sodium chloride (*sterile normal saline*), USP) and three applicator tips designed for use with all Irrisept and Irririnse bottles.

24. 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](tel: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.

25. 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*)

26. Is Irrisept on contract with any Group Purchasing Organizations (GPOs)?

Irrisept is under contract with:

- Vizient (*formerly Novation and MedAssets*)
- Premier Healthcare Alliance

27. Is there a reimbursement code for Irrisept?

No, a reimbursement code is not currently available.

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=MDTType&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/publications/Burns management.pdf](http://www.who.int/surgery/publications/Burns%20management.pdf)
8. Platt, J. & Bucknall, R.A. (1984). *An experimental evaluation of antiseptic wound irrigation.* *Journal of Hospital Infection.* 5:181-188.

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