FREQUENTLY ASKED QUESTIONS

1. **What is Irrisept?**
   Irrisept is a patented jet lavage system, containing low concentration chlorhexidine gluconate (CHG) 0.05%.

   It is a FDA cleared Class II medical device.

   The Irrisept system contents include Step 1 (Irrisept, 450mL, 0.05% CHG in sterile water, USP- 99.95%), Step 2 (Irririnse, 450mL, sterile normal saline, USP) and three applicator tips designed for use with all Irrisept and Irririnse bottles.

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 and debris.
   - The Irrisept solution contains 0.05% CHG which acts as a preservative to help inhibit microbial growth in the solution.

3. **Where can I use Irrisept?**
   Irrisept is cleared for use on wounds.

4. **Is Irrisept safe?**
   Irrisept has passed initial FDA safety testing for cytotoxicity, skin irritation and immune allergic response.[1] Ongoing testing is part of Irrisept's clinical program. Irrisept has also conducted safety testing for acute systemic toxicity and neurological toxicity.[2,3]

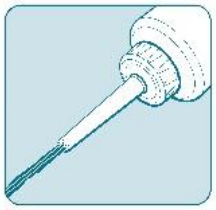
5. **Does Irrisept have any warnings and/or cautions?**
   Irrisept is contraindicated for patients with a known CHG allergy. Keep away from eyes and ear canals. If there is contact with these areas, rinse out promptly and thoroughly with water or normal saline. Discontinue use immediately if irritation sensitization or allergic reaction occurs.

6. **Is anyone allergic or sensitive to CHG?**
   Acute reactions to chlorhexidine are rare. The incidence of irritation and hypersensitivity is low when chlorhexidine is applied according to manufacturer's directions at its recommended concentrations.[4,5]

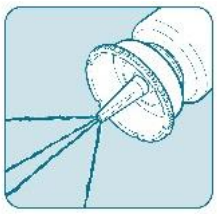
7. **Why does Irrisept packaging state "Use as directed by a physician. Rx Only."?**
   Irrisept is only available to licensed healthcare professionals. FDA regulations require Irrisept packaging to state: "Caution: Federal law restricts this device to sales by or on the order of a license healthcare 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.

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. The Irriprobe facilitates deep tissue wound debridement and cleansing. The LT Splatterguard is designed for debridement and cleansing of an abscess wound. The Splatterguard is used during wound debridement and cleansing and has no elongated tip.

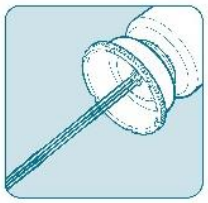
Irriprobe



LT Splatterguard



Splatterguard



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. **Can Irrisept be warmed prior to use?**
    Warming of the Irrisept system must be limited to no greater than 40°C (104°F) prior to use. Warming of Irrisept must not exceed 18 weeks. For further specifics regarding warming, please contact the Irrisept Clinical Team.

14. **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-403 meets a pH of 5.0-7.0 and each LOT of Irririnse meets a pH of 5.0-7.0. Further details and testing data are on file at Irrimax Corporation.

15. **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.

16. Can Irrisept be used in conjunction with negative pressure VAC therapy?

Wound cleansing and debridement is regularly performed prior to VAC therapy initiation or in conjunction with VAC therapy dressing changes. VAC therapy is not a debriding tool and is not a substitute for effective forms of debridement.[6] When using the Irrisept system in conjunction with VAC therapy, use Step 1 and Step 2 according to the Irrisept instructions for use. Initiate VAC therapy as ordered and follow VAC manufacturer's directions.

17. 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]

18. Can chlorhexidine be used for burns?

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

19. 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. Any further questions regarding mixing CHG, please contact the Irrisept Clinical Team to inquire.

CUSTOMER SERVICE AND ORDERING

20. 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

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

21. 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, sterile normal saline, USP) and three applicator tips designed for use with all Irrisept and Irririnse bottles.

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 major distributors:

- Cardinal
- Owens & Minor
- McKesson
- Henry Schein
- Medline
- AmerisourceBergen
- Mohawk

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

Irrisept is under contract with:

- MedAssets
- Novation
- Premier Healthcare Alliance.

25. 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.
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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.