Frequently Asked Questions about IrriSept and IrriSept O.R. Products

What is IrriSept

- **What is IrriSept?**
  IrriSept is the first and only FDA-cleared wound cleansing and debridement system containing Chlorhexidine Gluconate (CHG).
- **How does the IrriSept delivery system work?**
  IrriSept delivers irrigation fluid at ACEP-recommended pressure for wound cleansing and debridement. 450 mL of fluid can be delivered in less than 30 seconds. Proper use of the system reduces splatter and aerosolized contamination.
- **What different IrriSept products are available?**
  IrriSept is a two-step, single use system currently available in two configurations:
  IrriSept (MAX-302): intended for use in any non-sterile environment
  IrriSept O.R. (MAX-402): packaged in sterile Tyvek trays intended for use in sterile environments

Scientific Support

- **How safe is the IrriSept concentration?**
  The IrriSept system, at a concentration of 0.05% CHG, passed the FDA-required tests for cytotoxicity, skin irritation, and immune (allergic) response.[1]
- **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 chlorhexidine molecule to negatively charged bacterial cells results in a rapid rate of bacterial cell death.[2]
- **Has IrriSept been tested for bacterial persistence, and how long it is effective?**
  In blood agar plate tests performed by an independent laboratory, IrriSept destroyed and inhibited HA-MRSA, CA-MRSA, and Coagulase Negative Staphylococci for 14 days.[3]
- **Is CHG compromised by protein rich biomaterials?**
  No. CHG has a broad spectrum, rapid-acting, and persistent antimicrobial activity and is effective in the presence of blood and organic matter.
- **Is CHG, at the concentration used in IrriSept, effective against bacteria and fungi?**
  The 0.05% CHG in IrriSept has been shown effective in laboratory testing against a variety of bacteria and fungi, including MRSA and Pseudomonas.[3,4]
- **Can bacteria become resistant to CHG?**
  There is no documented resistance to CHG.
- **Has CHG been used previously in medical products?**
  Yes. Chlorhexidine-based antiseptics applied topically have been used globally for the last 60 years. In the US, many studies have been published supporting CHG-based antiseptics.

Device and Applicator Questions

- **Why wait one minute after IrriSept before application of IrriRinse?**
  One minute gives CHG time to bind with the tissue proteins and bacterial cell walls. In vivo studies showed a 2.83 log reduction of MRSA at one minute and a >6.74 log reduction of *Pseudomonas aeruginosa* at one minute.[5]
- **Why is there the rinse step?**
  The CHG concentration in IrriSept is considered non-toxic; however, the rinse step removes any unbound CHG that remains in the wound.
- **What applicators are available?**
  Applicator choice is determined by end-user preference.

SplatterGuard®
The SplatterGuard facilitates splatter protection and decreases aerosolized contamination during wound cleansing and debridement procedures.

LT SplatterGuard®
The LT SplatterGuard facilitates splatter protection and decreases aerosolized contamination during wound cleansing and debridement of abscesses.

IrriProbe®
The IrriProbe facilitates deep tissue wound cleansing and debridement in an operating room setting.

- **What can IrriSept replace in a surgical procedure?**
  IrriSept can replace standard saline irrigation for wound cleansing and debridement.
- **Can IrriSept be re-used?**
  No. IrriSept is designed as a single-use, disposable irrigation system.
- **What are the volume guidelines?**
  Increased volume with adequate pressure improves wound cleansing and results in better wound outcomes. Volumes of 50-100 mL per centimeter of laceration length or per square centimeter of a wound are commonly reported in the literature. Irrigation volume should take into consideration the characteristics and degree of wound contamination as well.
- **Can IrriSept be warmed?**
  We have aged IrriSept 402 at 40 degrees Celsius for 26 weeks and there has been no change in chemical composition. We do not anticipate any change in chemical composition at temperatures less than 40 degrees Celsius.
- **What is the shelf life of IrriSept?**
  IrriSept (MAX-302) has a two-year shelf life. IrriSept O.R. (MAX-402) currently has a one-year shelf life.
- **Why can't I mix my own?**
  IrriMax Corporation holds the rights to US and worldwide patents that provide broad protection for the use of CHG to irrigate wounds. IrriSept is an FDA-cleared product, manufactured to precise specifications (particularly given the critical percent concentration of CHG) in an FDA-approved facility in accordance with specific Good Manufacturing Practice regulations.

IrriSept Application

- **Can IrriSept be used in all procedures?**
  IrriSept is FDA-cleared for all wounds. A wound is defined as any break in the surface of the tissue. Examples of IrriSept use include: Orthopedic surgery, General Surgery, Plastic & Reconstructive Surgery, Cardothoracic Surgery, Neurologic Surgery, Surgical Site Infections (SSI's), Skin & Soft Tissue Infections (SSTI's), delayed closures, abscesses, deep traumatic wounds, wound dehiscence, Pilonidal cysts, lacerations, and burns. IrriSept should not be used for patients with a known CHG allergy. If IrriSept comes in contact with the eyes or ear canal, rinse with water or normal saline.
- **Is anyone allergic/sensitive to IrriSept?**
  There has been no reported allergy/sensitivity to IrriSept. Acute effects of chlorhexidine have been rarely reported and are associated only with high doses of chlorhexidine.[6] The incidence of irritation and hypersensitivity is low when chlorhexidine is applied at its recommended concentrations.[6]
- **Does IrriSept impact the integrity of a breast implant?**
  "I have used IrriSept on hundreds of my breast augmentations since 2009 prior to placing the sterile implant in the breast pocket. IrriSept has no impact on the implant and is non-toxic to soft tissue." Dr. Roger Brill, American College of Plastic Surgery Board Certified and Clinical Associate Professor University of Florida College of Medicine.
- **Can IrriSept be used in conjunction with negative pressure VAC therapy?**
  Yes. IrriSept can be used to cleanse and debride wounds during VAC therapy dressing changes.
- **Can IrriSept be used for burns?**
  Chlorhexidine preparations at 0.05% have been used extensively in the management of burns for cleansing.[6]
- **How does IrriSept affect granulation tissue?**
  Literature suggests that slight granulation changes that may occur with CHG irrigation may 'kick start' the healing process.[7] CHG irrigation did not delay wound healing and actually reduced inflammation[7]. CHG has been reported cytotoxic when exposed to fibroblasts in vitro; however, Sanchez (1988) demonstrated that the cytotoxicity observed in vitro does not occur in vivo. An infected wound model showed 0.05% CHG actually accelerated the rate of healing compared with the saline control.[8]

Customer Service

- **How do I obtain a sample?**
  Request a sample by emailing cs@irrisept.com or calling *770-807-8445*, providing your healthcare institution name and contact information. IrriSept is regulated as a prescription product and can only be sampled by qualified healthcare professionals.
- **How do I order?**
  Contact our customer service department directly at *770-807-8445* and our sales team will work with you and your preferred distributor to facilitate your initial order. IrriSept can be ordered through these national distributors: *Cardinal, McKesson, Medline and Owens & Minor*.
- **Can the department be reimbursed for IrriSept?**
  No reimbursement code is 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. Chawner, J.A., Gilbert, P. (1989). Interaction of the bisbiguanides chlorhexidine and alexine with phospholipid vesicles: evidence for separate modes of action. J Appl Bacteriol. 66(3):253-258.
3. Laboratory Testing Records, "Chlorhexidine Gluconate (CHG) Bacterial Study Report," on file at IrriMax Corporation.
4. Laboratory Testing Records per USP <51>, Antimicrobial Effectiveness Testing, on file at IrriMax Corporation.
5. Laboratory Testing Records, "Time Kill Study GLP Report," on file at IrriMax Corporation.
6. Denton, G. (2001). Chlorhexidine. In: Block, S. ed. *Disinfection, sterilization, and preservation*. 5th ed. Lippincott Williams & Wilkins; Philadelphia, PA. 321-336.
7. Hampton, S. & Collins, F. (2004). *Tissue viability: the prevention, treatment, and management of wounds*. Whurr Publications; Philadelphia, PA. 150.
8. Sanchez, I., Swaim, S.F., Nusbaum, K.E., et al. (1988). Effects of chlorhexidine-diacetate and povidone-iodine on wound healing in dogs. *Vet Surg*; 17:291-295.