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IrriSept® Fact Sheet

OVERVIEW

IrriSept® is the first and only FDA-cleared wound debridement and cleansing system containing chlorhexidine gluconate (CHG). The 0.05 percent CHG concentration in IrriSept has been shown effective in laboratory testing against a variety of bacteria and fungi, including Staph and methicillin-resistant *Staphylococcus aureus* (MRSA).^{1,2} The solution has passed FDA-required tests for cytotoxicity, skin irritation, and immune (allergic) response.³

APPLICATIONS

Instead of cleansing a wound with just normal saline, healthcare professionals can apply IrriSept with CHG directly to surgical or deep wounds, burns, abrasions, lacerations, SSTIs including abscesses, delayed closures, dehiscence, pilonidal cysts, and infected wounds. IrriSept is designed for use in surgical and non-surgical environments, including operating room settings, wound care centers, emergency departments, burn units, and other healthcare settings.

UNIQUE ATTRIBUTES

- Contains 0.05 percent CHG
- Faster and more efficient than traditional syringe irrigation
- Reduces biohazard contamination and renders it inert⁴

HELPS ADDRESS GROWING HEALTHCARE ISSUES

- Surgical Site Infections (SSIs)
 - More than 780,000 SSIs reported annually, averaging \$30,000 per occurrence.⁵
 - MRSA SSIs cost a hospital > \$60,000 per occurrence, add an average 16 days to hospitalization and increase mortality rates.⁶
 - SSI rates are as high as 23 percent in certain procedures.⁷
- Healthcare-Associated Infections (HAIs)
 - According to the Centers for Disease Control and Prevention, 1.7 million people per year acquire an HAI, which results in 99,000 deaths -- the equivalent of 271 people each day. HAIs cause more deaths annually than AIDS, breast cancer, and auto accident deaths combined.⁸

- Skin and Soft Tissue Infections (SSTIs)
 - 14.2 million cases of SSTIs reported annually.⁹
 - In many U.S. cities, MRSA is the most common pathogen isolated in the emergency department from patients with SSTIs and is found in approximately 61 percent of excised abscesses.¹⁰
 - 3.4 million emergency department visits can be attributed to SSTIs each year and, of these, 14 percent (466,000) result in hospitalization.¹¹

HELPS ADDRESS GROWING HEALTHCARE ISSUES (continued)

- Healthcare Worker Safety
 - MRSA nasal colonization among emergency department staff is 15 percent compared to 1.5 percent (10 times the rate) for the general public.^{12, 13}
- Alleged wound complications represent 19 to 24 percent of healthcare malpractice claims.¹⁴

EASY-TO-USE TWO-STEP DELIVERY SYSTEM

- Step 1: Debride and cleanse. Through bottle compression, the patented IrriSept system delivers 450mL of solution in less than 30 seconds to effectively loosen and remove wound debris and bacteria without harming underlying tissues.
- Step 2: Rinse one minute later with IrriRinse®.

The patented delivery system, which is faster and more efficient than traditional syringe irrigation, ensures compliance with ACEP guidelines for irrigation pressure and volume.

OTHER FEATURES

- The surgical product -- labeled IrriSept O.R. -- includes a choice of three irrigation applicators:
 - SplatterGuard® with four nozzles;
 - LT SplatterGuard®, featuring a long-tip with four angled nozzles, designed specifically for abscess cleansing;
Both provide splatter protection and decrease aerosolized contamination during wound cleansing and debridement procedures, and
 - IrriProbe™ for deeper wound cleansing
- The non-surgical product -- labeled IrriSept -- includes the same applicators with the exception of the O.R.-specific IrriProbe.

DISTRIBUTION

IrriSept can be purchased directly from IrriMax or from Medline (www.medline.com), the nation's largest privately held and fastest-growing distributor of medical and surgical supplies in the U.S.

IRRIMAX CORPORATION

Founded in 1994, Irrimax[®] Corporation develops and markets wound irrigation solutions using a patented, innovative delivery method that produces unmatched efficacy and safety. The medical device company's goal is to improve patient outcomes by treating and preventing infections, as well as to increase the safety of healthcare workers. Its flagship product, Irrisept[®], is the first and only FDA-cleared wound debridement and cleansing system containing CHG. Continual innovation and ongoing clinical research guide the development of Irrimax products. For more information, visit www.irrisept.com.

- ¹ Laboratory Testing Records per USP <51>, Antimicrobial Effectiveness Testing, on file at Irrimax Corporation
- ² Laboratory Testing Records, "Chlorhexidine Gluconate (CHG) Bacterial Study Report," on file at Irrimax Corporation
- ³ Biocompatibility compliance tests completed per FDA's Blue Book Memorandum G95-1 and ISO 10993-1, Biological Evaluation of Medical Devices, on file at Irrimax Corporation
- ⁴ Laboratory Testing Records, Comparative Study to Demonstrate the Effectiveness of Irrisept[®] at Eradicating MRSA in Splatter Generated from Wound Irrigation, Unpublished Laboratory Report (Sept 2010), Aerosol Research & Engineering Laboratories, Lenexa, KS, on file at Irrimax Corporation
- ⁵ Deutsch, R, "56 Hospitals Collaborate to Prevent Surgical Infections," The American Health Quality Association, June 2005
- ⁶ Anderson, DJ et al, "Clinical and Financial Outcomes Due to Methicillin Resistant Staphylococcus aureus Surgical Site Infection: A Multi-Center Matched Outcomes Study," PLoS One, Dec. 2009
- ⁷ Itani et al, "Comparison of Laproscopic and Open Repair With Mesh for the Treatment of Ventral Incisional Hernia," Arch Surg, April 2010
- ⁸ Klevens et al, "Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002," CDC/Public Health Reports, March-April 2007
- ⁹ Hersh AL, Chamer HR, Maselli JH, et al. National Trends in Ambulatory Visits and Antibiotic Prescribing for Skin and Soft-Tissue Infection, Arch Intern Med 2008;168:1585-91
- ¹⁰ Moran et al. Methicillin-Resistant S. aureus Infections among Patients in the Emergency Department, N. Engl J Med 2006; 355:666-74
- ¹¹ Pallin DJ et al. Increased ED Visits for SSTI, and Changes in Antibiotic Choices, during the Emergence of CA-MRSA, Annals of Emerg Med, 2007
- ¹² Bisanga et al. A Prevalence Study of Methicillin-Resistant Staphylococcus aureus Colonization in Emergency Department Health Care Workers, Annals of Emerg Med, 2008
- ¹³ Gorwitz RJ, Kruszon-Moran D, McAllister SK, et al. Changes in the prevalence of nasal colonization with Staphylococcus aureus in the United States, 2001-2004, J Infect Dis 2008; 197:1226-34
- ¹⁴ Gardner et al. Avoidable Errors in Wound Management. ACEP Foresight, October 2002

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