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Irrisept: Redefining Irrigation

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**Surgical Site Infections**

- Surgical site infections (SSIs) are the costliest hospital infections among hospitalized patients. In the U.S. approximately 300,000 SSIs occur yearly, representing 13% of healthcare-associated infections.
- SSIs have a major impact on hospital’s financial performance. An average cost of a SSI is approximately $30,000. The cost of using IrriSept at $60 on 500 patients is $30,000. With the average cost of a single SSI at $30,000, a reduction of just one SSI occurrence could cover the total cost of using IrriSept on approximately 500 patients.

**Resources:**


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**ABOUT THE IRRISEPT**

- IrriSept is the only FDA-cleared device that delivers a pressurized solution containing Chlorhexidine Gluconate (CHG) for cleansing and debridement. As a final rinse, prior to closure in surgical procedures, IrriSept has the potential to help reduce SSIs and associates treatment costs. IrriSept was developed with the goal of becoming the “Standard of Care” and improving patient outcomes.
- IrriSept has a wide range of activity against gram positive and gram negative bacteria, fungi, and viruses. It has demonstrated antimicrobial efficacy and persistence in laboratory testing.

**WHAT IS IRRISEPT?**

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

**RECENT STUDIES USING IRRISEPT TO REDUCE SURGICAL SITE INFECTIONS IN COLORECTAL SURGERY**

University of South Florida conducted a study at Tampa General Hospital

- The study demonstrated a significant decrease in SSIs in colorectal operations with the consistent use of IrriSept during a 7 month period.
- A total of 196 qualifying cases were performed prior to the IrriSept intervention and 197 during the trial period. A total of 27 SSIs occurred in each of the time periods. Table 1: demonstrates the number and rates of SSIs occurring during each time period and the difference between surgeons.

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**WHAT IS THE POTENTIAL IMPACT ON PATIENTS AND HOSPITALS?**

- Intrapерitoneal Organ Toxicity: The final report states that, under conditions of the study, there were no significant adverse findings associated with the test article in the tissue evaluated.
- Acute Systemic Toxicity: The study objective was to demonstrate safety if IrriSept without normal saline rinse through evaluation of systemic toxicity in a mouse model. There was no mortality and no necropsy at 7 days and there was no evidence of systemic toxicity from either portions of the test article.
- Neurotoxicity: The study objective was to demonstrate safety if the IrriSept solution without normal saline rinse through evaluation of systemic and neurotoxicity and local effects after implantation in a chronic rabbit dorsal laminaotomy model. Results demonstrated that the IrriSept solution without a rinse is a non-irritant, is comparable to saline control when evaluated histologically, and therefore did not exhibit neurotoxicology.
- Hemolysis: Analysis of the study endpoints indicate that IrriSept does not have more hemolytic potential than normal saline.
- Pharmacokinetics: Administration of IrriSept does result in measurable levels of glucanate in the blood. Those levels rapidly decrease within 3 hours of administration, almost to baseline. The administration of IrriSept did not result in any observable adverse effects with respect to peritoneal organs.

**SAFETY CONSIDERATIONS AND POST-MARKETING STUDIES**

IrriSept has conducted post-marketing studies that have generated safety testing regarding cytotoxicity, sensitization, and irrigation.

**OTHER CONSIDERATIONS**

Financial implications are not the only concern for hospitals and patients. There are many other potentially adverse consequences as a result of high SSIs rates:

- Additional antibiotic usage
- Potential liability issues
- Increased re-admissions and overall length of stay
- Potential reputational issues for the facility and surgeon

**Presented by:** Nicole Koenig, RN, CNOR, TNCC
St. Cloud Hospital, St. Cloud, MN

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**Table 1:**

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**Month-Year and Rate/100 Procedures**

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