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# Irrisept: Redefining Irrigation

Nicole Koenig

*St. Cloud Hospital, CentraCare Health, koenign@centracare.com*

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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.

## SCH SURGICAL SITE INFECTION RATES FOR Q3 FY17 (JAN-MAR 2017)

Primary focus on decreasing infection rates in colon surgery patients

St. Cloud Hospital		FY 2017			
I. Overall Cesarean Results		Surgical Site Rates Per NHSN Operative Procedure Category			
		Q3 FY 2017	FY 2017	Q3 FY 2017	FY 2017
Cesarean Births		170	597		
Overall Cesarean Birth Site Infections		0	6	0.00%	1.01%
Cesarean Births (not Cases)		0	1	0.00%	0.17%
Cesarean Births (OP Identified Cases)		0	3	0.00%	0.84%

  

II. Results By NHSN Operative Procedure Category					
Numbers of Procedures	Number of Surgical Site Infections		Post-Op Site Infection Rate		NHSN Pooled Mean
	Q3 FY 17	FYTD17	Q3 FY17	FYTD17	
(October-December)					
CBGB					
Coronary artery bypass graft with chest & donor site incisions	83	0	2	0.00	0.81
2.94					
COLO					
Colon surgery; does not include rectal operations	86	10	21	11.63	7.61
5.56					
C-SEC					
Cesarean section/ Cesarean birth	170	0	6	0.00	1.01
1.84					
FUSN					
Spinal fusion	129	1	5	0.78	1.40
1.54					
HER					
Hem biopsy	37	1	1	2.70	1.09
2.25					
HPRO					
Hip prosthesis arthroplasty of hip	170	3	4	1.76	0.91
1.27					
HYST					
Abdominal hysterectomy	44	0	1	0.00	1.01
1.65					
KPRO					
Knee prosthesis arthroplasty of knee	166	0	5	0.00	0.98
0.89					
LAM					
Laminectomy	263	0	10	0.00	1.31
1.02					

## Resources:

- Edmiston, C.E. & Leaper, D.J. (2016). Intra-Operative Surgical Irrigation of the Surgical Incision: What Does the Future Hold-Saline, Antibiotic Agents, or Antiseptic Agents? *Surgical Infections*, 17(6).
- Edmiston, C. E., Bruden, B., Rucinski, M. C., Henen, C., Graham, M.B., and Lewis, B. L. (2013, 05). Reducing the risk of surgical site infections: Does chlorhexidine gluconate provide a risk reduction benefit? *American Journal of Infection Control*, 41(5).
- Love, K. (2016). Patient Care Interventions to Reduce the Risk of Surgical Site Infections. *AORN Journal*, 104(6), 506-515.
- Shams, W., Hanley, G., Orvik, A., Lewis, N., & Shurbaji, S. (2015). Peritoneal lavage using CHG at the end of colon surgery reduces postoperative intra-abdominal infection in mice. *Journal of Surgical Research*, 195(1), 121-127.
- Spencer, M. (2016). Overview of Recent Issues and Advances in Infection Prevention. *AORN Journal*, 104(6), 502-505.

## 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.



# Irrisept

Redefining Irrigation

## 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 trail 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.

Table 1:	Surgeon 1: Consistent Use of Irrisept	Surgeon 2 & 3: Inconsistent Use of Irrisept	p-value
Pre-intervention Period SSIs/Cases (Rate)	13/67 (19%)	14/129 (11%)	0.32
Irrisept Trial Period SSIs/Cases (Rate)	7/58 (12%)	20/139 (14%)	0.0002
p-value	0.013	0.0137	

Month-Year and Rate/100 Procedures

August 2015	5.88
September 2015	6.21
October 2015	3.24
November 2015	2.13
December 2015	2.65
January 2016	3.47
February 2016	4.37
March 2015	3.33

April 2016	1.28
May 2016	1.49
June 2016	2.43
July 2016	1.05
August 2016	2.24
September 2016	2.01
October 2016	3.18
November 2016	1.09

## 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:

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

## SAFETY CONSIDERATIONS AND POST-MARKETING STUDIES

Irrisept has conducted post-marketing studies that have generated safety testing regarding cytotoxicity, sensitization, and irrigation. The testing data is summarized below:

- Intraperitoneal 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 the safety of Irrisept 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 neurological toxicity and local effects after implantation in a chronic rabbit dorsal laminectomy 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 neurological toxicity.
- 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 gluconate 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.

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