

CleanCision™ Clinical and Pre-Clinical Study Publication and Presentation Summary

STUDY TITLE

KEY FINDINGS / CONCLUSIONS

PRE-CLINICAL

The Efficacy of a Novel Surgical Device in Preventing Intraoperative Wound Contamination in an In Vivo Porcine Model¹

- Tissue protected by the device yielded exponentially lower levels of E. coli growth compared to exposed surface of the device.
- Use of the device, both with and without irrigation, was associated with exponential reduction in quantitative bacterial load compared to the control wounds with no device, with limited growth after wound closure in the pigs receiving irrigation.
- There were no adverse events and histology results showed no significant damage to tissue.
- In a porcine model using CleanCision with Indocyanine Green (ICG) as the irrigation fluid, fluorescence was observed along the wound edge and within the surrounding abdominal wall after device removal.
- There was >20% local uptake of ICG dye at the wound edge and 8 cm radius around the incision.

An Innovative Irrigating Wound Protector for Colorectal Surgery⁵

CLINICAL

A Novel Wound Retractor Combining Continuous Irrigation and Barrier Protection Reduces Incisional Contamination in Colorectal Surgery²

- Use of the device was associated with a 66% reduction in overall bacterial contamination at the protected incision vs exposed surface of the device (34.5% vs 11.9%, p<0.001) and a 71% reduction in enteric bacterial contamination (33.3% vs 9.5%, p<0.001).
- Use of the device resulted in an 86% reduction in pre-existing skin flora contaminants that were present despite sterile skin prep (16.7% vs. 2.4%, p<0.001).
- Low incisional SSI rate (2.3% in the primary analysis and 1.2% in those completing the protocol).
- No device-related adverse events.

Impact of a Novel Surgical Wound Protection Device on Observed versus Expected Surgical Site Infection Rates after Colectomy Using the National Surgical Quality Improvement Program Risk Calculator³

- The observed rate of SSI in a prospective study was 3.7% (4/108) compared to an expected rate of 9.5% in the same patient population utilizing the ACS-NSQIP risk calculator.
- The observed/expected ratio was 0.39, which demonstrates a 61% decrease in SSI with the use of the device (3.7% vs 9.5%, p=0.04).

ECONOMIC

Interventions and Innovation to Prevent Surgical Site Infection in Colorectal Surgery: A Cost-Effectiveness Analysis.⁴

- Use of dual-ring wound protection devices, including CleanCision, resulted in an estimated cost savings of 2.2 million dollars per 1000 patients, as well as health benefits of 230 quality-adjusted life-years (QALYs) per 1000 patients in colorectal surgery.
- Clinical data utilizing the CleanCision device showed that irrigating wound protection devices remain cost-effective at a price threshold of over \$2,000.

PUBLICATIONS

1. Suh I, Long SA, Coe J, Koehler J, Fry D, Welton ML. The Efficacy of a Novel Surgical Device in Preventing Intraoperative Wound Contamination in an In Vivo Porcine Model. *J Laparoendosc Adv Surg Tech A*. 2018;28(4):445-451.
2. Papaconstantinou HT, Ricciardi R, Margolin DA, et al. A Novel Wound Retractor Combining Continuous Irrigation and Barrier Protection Reduces Incisional Contamination in Colorectal Surgery. *World J Surg*. 2018;42(9):3000-3007.
3. Papaconstantinou HT, Birnbaum EH, Ricciardi R, et al. Impact of a Novel Surgical Wound Protection Device on Observed versus Expected Surgical Site Infection Rates after Colectomy Using the National Surgical Quality Improvement Program Risk Calculator. *Surg Infect (Larchmt)*. 2018.
4. Chomsky-Higgins K, Kahn JG. Interventions and Innovation to Prevent Surgical Site Infection in Colorectal Surgery: A Cost-Effectiveness Analysis. *Journal of Surgical Research*. 2019;235:373-382.

ABSTRACTS & POSTERS

5. Yelika SB, You K, Gachabayov M, Lee KP, Abbas SK, Bergamaschi RCM. An Innovative Irrigating Wound Protector for Colorectal Surgery. Poster presented at: NYSCRS 2017; New York, NY. Suh I, Coe J, Koehler J, Welton M. Microbiological Analysis and Clinical Feasibility of a Novel Device to Prevent Surgical Site Infection in Colorectal Surgery. Poster presented at: SAGES 2017; Houston, TX.
- Suh I, Coe J, Koehler J, Welton M. Microbiological Analysis and Clinical Feasibility of a Novel Device to Prevent Surgical Site Infection in Colorectal Surgery. Poster presented at: SAGES 2017; Houston, TX.
- Papaconstantinou HT, Ricciardi R, Margolin D, et al. Impact of Novel Wound Protection Device on Observed vs. Expected Surgical Site Infection Rates Following Colectomy Using the National Surgical Quality Improvement Program Risk Calculator. Paper presented at: WSA 2017 Annual Meeting 2017; Scottsdale, AZ.

PRESENTATIONS

Papaconstantinou HT, Ricciardi R, Margolin DA, et al. A Novel Surgical Device Combining Continuous Intraoperative Wound Irrigation and Barrier Protection Markedly Reduces Incisional Contamination in Colorectal Surgery. Paper presented at: American Society of Colon and Rectal Surgeons Annual Scientific Meeting 2017; Seattle, WA.