

Exploring a New Class of Advanced Technology to Fight the Sources of Surgical Site Infection

This paper explores a new class of advanced technology, the irrigating wound protector, which is designed to fight and defend against the sources of surgical site infection.

It examines the benefit of using this technology as part of a rigorous and consistent approach to reducing the risk of surgical site infection.

Executive Summary

Surgical site infection (SSI) is a major source of morbidity following surgery, particularly in high-risk abdominal procedures where over 15% of patients may develop an infection.¹⁻⁴ These patients suffer, and the infections result in significant healthcare costs and penalties. Intraoperative contamination of the wound during abdominal surgeries is the leading cause of SSI, underscoring the need to focus more intently on intraoperative infection prevention strategies. Over the past two decades there has been much emphasis on SSI prevention with zero preventable surgical infections emerging as an aspirational goal.

This paper explores a new class of advanced technology, the irrigating wound protector, which is designed to fight and defend against the sources of surgical site infection. It examines the benefit of using this technology as part of a rigorous and consistent approach to reducing the risk of surgical site infection.

From an infection prevention perspective, the irrigating wound protector falls under the category of what infection prevention expert Sue Barnes, RN terms “plus measures” for SSI prevention. Ms. Barnes defines Plus Measures as infection prevention practices and products that are supported by less than category 1 level evidence, which can be considered when there is no associated risk to the patient, and when zero sustained preventable infections has yet to be achieved.⁵

An innovative plus measure that is now available for abdominal surgical procedures is CleanCision™, the first device to combine wound retraction, protection, controlled wound irrigation and fluid removal in a single device to provide active cleansing of the wound throughout the surgical procedure.

The Unmet Need: A Way to Fight Infection at the Source

Healthcare associated infections (HAIs) have become an area of national attention due to the associated financial burden placed on the healthcare system. SSIs are the most common and costly of all HAIs.⁶

The overall incidence of SSI is estimated to be between 2 and 5%.⁷ However, patients undergoing high-risk abdominal surgery such as colorectal surgery, have reported SSI rates in the range of 15-30%.¹⁻⁴

SSI is associated with increased length of stay⁸, higher re-admission rates⁹, required reoperation¹⁰, and increased mortality.¹¹ The incremental cost of a single SSI in high-risk abdominal surgery is estimated to be \$19,000.^{4,9} Although harder to quantify, SSIs also significantly impact patients' quality of life.¹²

SSIs are the most common and costly of all HAIs.⁶

Wound contamination is the root cause of SSI, yet after decades of national SSI prevention focus, surgical teams still struggle to comprehensively mitigate this risk. There is a direct correlation between wound contamination and SSI's. Researchers report that nearly 50% of abdominal incisions are contaminated with 20% of contaminated wounds leading to infection.¹³ (Figure 1a) Abdominal surgery frequently involves entry into the gastrointestinal tract. The Centers for Disease Control and Prevention (CDC) has reported data showing that 74% of surgical site infections in abdominal surgery can be attributed to the patient's own gut bacteria (enteric contamination).¹⁴ (Figure 1b)

Current surgical technologies do not adequately eliminate contamination, leaving critical gaps where patients remain vulnerable to infection. CleanCision was specifically designed to address these gaps by focusing on intra-operative contamination.

Wound contamination is the root cause of SSI

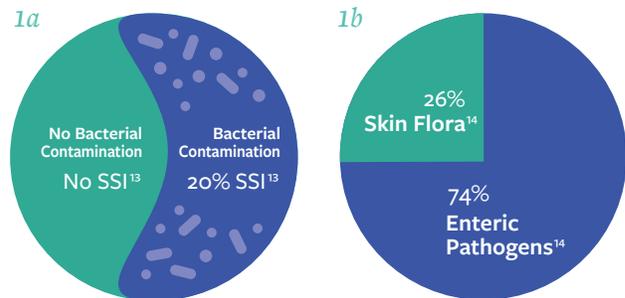


Figure 1: Abdominal wound contamination summary
a) Correlation between contamination and surgical site infection
b) Category of organism causing surgical site infections (Skin vs. Enteric)

The CleanCision Novel Approach: An Integrated, Intuitive System

CleanCision is a new advanced infection control technology, the first to combine wound retraction, irrigation, protection, and suction in a single device, providing continuous and consistent cleansing of the wound throughout the surgical procedure.

Developed by surgeons and infection control experts, CleanCision is an intuitive, easy-to-use irrigating wound protection system that seamlessly integrates into evolving surgical workflow and infection control procedures.

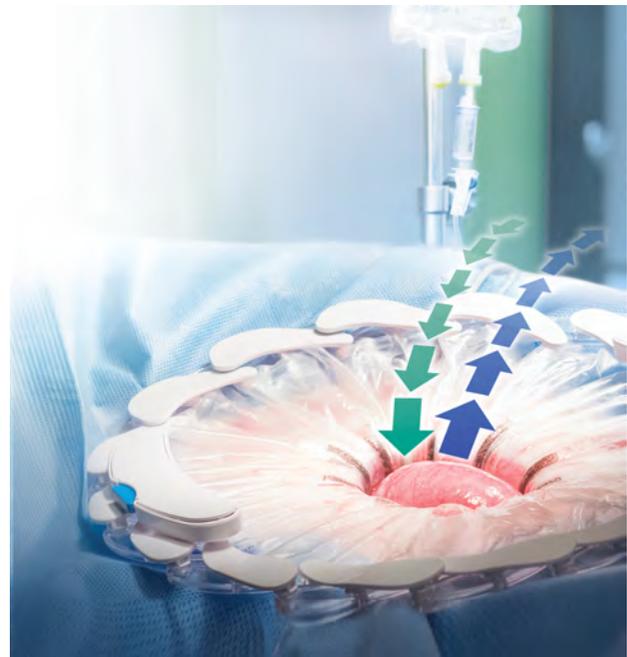


Figure 2: CleanCision Device

Unlike traditional methods, CleanCision continuously and consistently clears harmful bacteria throughout surgery when the threat of wound contamination is at its highest.¹⁵ As shown in Figure 3, the CleanCision system includes: surgical retraction, wound barrier protection, irrigation of wound edges and fluid removal.

CleanCision Features:

1. Surgical Retraction

Employing a familiar form factor, the product is compatible with established surgical techniques and doesn't require any changes in practice to be implemented into infection control protocols.

- A flexible bottom ring is squeezed and inserted into the abdominal cavity.
- A soft, conformable plastic sheath covers the wound edges.
- An expanding top ring is left above the skin and pulled open to retract the wound.

2. Wound Barrier Protection

The wound edges are protected from direct contamination by the dual-layer, impermeable sheath, which provides a physical barrier from the surgical field.

3. Irrigation of Wound Edges

Fluid irrigation is delivered from an external fluid bag hung above the patient and through the included tubing set into the product via gravity. The fluid then exits the outside of the sheath onto the wound edge for continuous cleansing throughout the duration of the surgery.

4. Fluid Removal

After cleansing the wound edge, the irrigation fluid along with any contamination washed away from the tissue are removed through the bottom ring via connection with the hospital's standard vacuum suction mechanism for continuous evacuation of potentially infectious material.

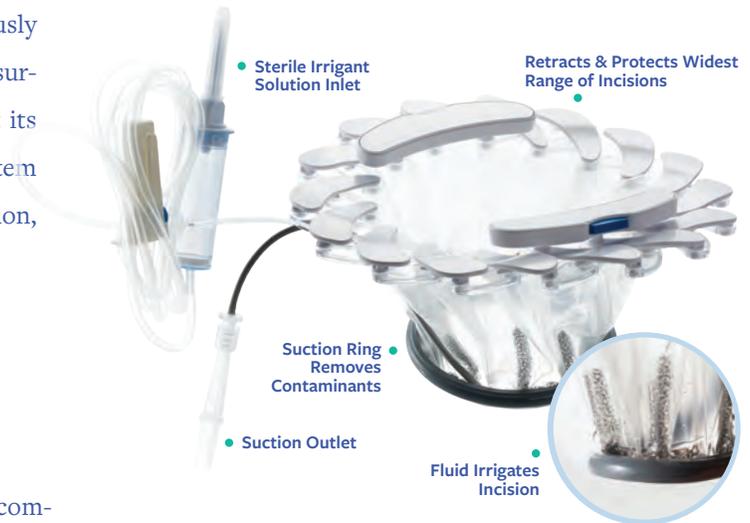


Figure 3: *CleanCision System Features*



Figure 4: *Surgical retraction and wound barrier protection using the CleanCision device*



Figure 5: *Wound edge irrigation and fluid removal*

Closing Critical Gaps in SSI Care

Despite all the effort taken to reduce SSI risk during the operative time period, critical gaps still remain. These gaps include: incomplete skin antisepsis, trapping and incomplete clearance of pre-existing or intraoperative contamination by passive wound protectors, spreading of bacteria by manual irrigation, and issues with the tissue concentrations and re-dosing of prophylactic IV antibiotics – not to mention difficulties simultaneously and consistently implementing strategies proven to reduce SSI risk in this environment. CleanCision was designed to combine surgical best practices to address these critical gaps.

CleanCision was designed to combine surgical best practices to address critical gaps in SSI Care.

Gaps During Operative Time Period Addressed by CleanCision

- I Surgeons must choose between wound protection and irrigation
- II Prophylactic IV antibiotics at the wound edge can fall below effective levels
- III Incomplete skin antisepsis introduces bacteria into the wound
- IV Passive wound protectors can trap contamination
- V Manual irrigation is disruptive to surgical workflow
- VI Manual irrigation can spread contamination

I Surgeons must choose between wound protection and irrigation

Gap Description:

One of the greatest limitations of current intraoperative practices to reduce intraoperative wound contamination is that wound protection and wound irrigation cannot be performed simultaneously. Recent meta-analyses have demonstrated that both wound protection and wound irrigation individually provide potential benefit in reducing surgical infection risk.^{16,17} However, surgeons must choose during the procedure whether they want to place a physical barrier over the wound edge to protect it from potential sources of contamination or if they want to irrigate the wound edges to flush away any contamination.

How CleanCision Addresses this Gap:

CleanCision was specifically designed to combine these two infection control best practices into a single device and allow for ***simultaneous wound protection and wound irrigation*** to address even the most challenging surgical environments.

II Prophylactic IV antibiotics at the wound edge can fall below effective levels

Gap Description:

Prophylactic IV antibiotics have been demonstrated to lower SSI and are recommended as standard of care in recent SSI guidelines.^{6,18-19, 22} However, it has been shown that concentrations at the wound edge can fall below effective levels.²⁰ IV antibiotic penetration to the wound edge may be of particular challenge in obese patients.²¹ This can allow for proliferation of bacteria at the wound edge.

How CleanCision Addresses this Gap:

CleanCision ***actively irrigates the wound edge to help clear any pre-existing or intraoperative contamination*** that may be present in order to help prevent bacterial proliferation.

III Incomplete skin antisepsis introduces bacteria into the wound

Gap Description:

A critical method of reducing resident and transient bacteria at the wound site is pre-operative surgical skin prep. This is recommended by all recent SSI prevention guidelines including the US Centers for Disease Control and Prevention.^{6,18-19,22} While there is strong evidence to support antiseptic skin preparation, results are dependent upon the prep solution and proper application technique. In a meta-analysis looking at studies that evaluated bacterial colonization following skin antisepsis, an average of 24% residual contamination was reported.²³

How CleanCision Addresses this Gap:

In a multi-center study utilizing CleanCision during elective colorectal surgery, after antiseptic preparation of the skin, 17% of subjects had skin organisms present on the wound surface at the time the device was placed.²⁴ In the same study, the CleanCision device provided active cleansing of the wound surface after device placement. ***The number of patients with skin flora present was shown to be reduced by 86% with use of the CleanCision device*** from 17% at the time of device placement to 2% at the time of device removal ($p < 0.001$).²⁴

IV Passive Wound Protectors can trap contamination

Gap Description:

Traditional passive wound protectors can trap bacteria that is present at the time of device placement, either from incomplete skin antisepsis, as described above, or from contaminated surgical fields encountered in trauma and acute care surgeries. Passive wound protectors are also not designed to clear that contamination which could allow proliferation of that bacteria during the course of the procedure. Furthermore, passive wound protectors are unable to clear bacteria that may get to the wound edge during the surgical procedure.

How CleanCision Addresses this Gap:

CleanCision clears contamination during surgery by actively cleansing the wound edge throughout the procedure.

V Manual irrigation is disruptive to surgical workflow

Gap Description:

Irrigation, a common practice during surgery, is done manually today. Manual irrigation is difficult to implement throughout the surgery due to break in workflow and therefore is typically limited to the end of the procedure.

How CleanCision Addresses this Gap:

The CleanCision device is placed during the surgical procedure providing **constant, consistent, and controlled irrigation** of the wound throughout the surgical procedure. This enhances surgeon focus, while ensuring continuous dilution and clearance of potentially infectious contamination from the wound edge.

VI Manual irrigation can spread contamination

Gap Description:

Manual surgical irrigation, particularly high pressure, can result in splashing and transfer of bacteria to surrounding areas.²⁵

How CleanCision Addresses this Gap:

The CleanCision device provides constant, **contained irrigation of the wound with no risk of splashing**. The device connects to the hospital's standard suction system to remove any excess fluid keeping the irrigation contained to the wound edge.

Body of Evidence: Supporting the Use of Irrigating Wound Protection

There is both pre-clinical and clinical data to support the use of the CleanCision. Brief summaries of the most relevant studies are included below.

Mechanism of Action Study

An Innovative Irrigating Wound Protector for Colorectal Surgery²⁶

SB Y, You K, Gachabayov M, KP L, SK A, Bergamaschi R. Paper presented at: NYSCRS2017; New York, NY.

A porcine model was used to study the distribution of the irrigation fluid from the CleanCision device around the wound edge.

Study Objective:	To evaluate the vascular microcirculation at the wound edge using the CleanCision System with Indocyanine Green (ICG) irrigation
Study Design:	A qualitative analysis of irrigation distribution using ICG angiography in a porcine model
Subjects:	A 86kg pig with a 9cm surgical incision located in the abdomen
Outcome Measures:	Evaluation of ICG uptake at the wound edges and surrounding abdominal wall
Results:	A >20% local uptake of ICG dye was observed at the wound edge with an 8cm radius around the incision.

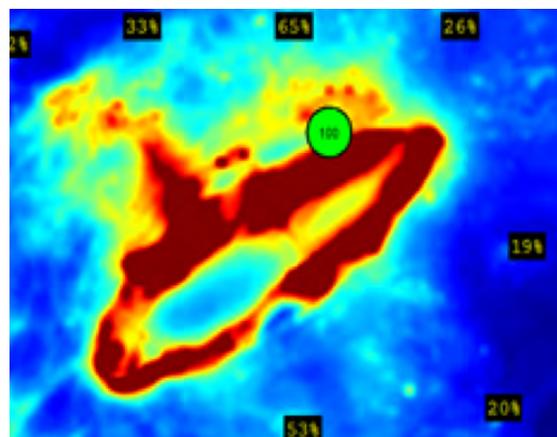


Figure 6: Fluorescence heat map describing the concentration of ICG at the wound edge to the adjacent abdominal wall

Supporting Clinical Evidence for CleanCision

A Novel Wound Retractor Combining Continuous Irrigation and Barrier Protection Reduces Incisional Contamination in Colorectal Surgery²⁴

Papaconstantinou HT, Ricciardi R, Margolin DA, et al. World Journal of Surgery. 2018.

In a multi-center clinical study conducted in elective colorectal surgery, **CleanCision was shown to reduce overall contamination by 66% (p<0.001) and enteric contamination by 71% (p<0.001).**²⁴ This study also demonstrated the ability to reverse pre-existing skin contamination. A comparison of the wound edge prior to device placement compared to after device removal, showed an 86% reduction in skin organisms after the use of the device (p<0.001). As discussed previously, Fa si Oen showed that 20% of incisions that are contaminated become infected.¹³ This direct correlation between contamination and infection was confirmed in this study, which showed 2 out of 10 (20%) of patients with contamination present on the wound surface developed a wound SSI compared to 0 of 74 patients without contamination developed a wound SSI.

Study Objective:	To evaluate the safety and efficacy of CleanCision in protecting surgical incisions from intraoperative contamination when used during colorectal surgery
Study Design:	A prospective, non-randomized study at 7 large tertiary-care referral centers
Subjects:	86 patients undergoing elective colorectal resection
Outcome Measures:	<ul style="list-style-type: none"> - Rate of enteric and overall bacterial contamination on the exposed incision edge as compared to the protected incision edge - Rate of surgical site infection (SSI) - Serious adverse events directly attributable to the device
Results:	<ul style="list-style-type: none"> - 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). - The incisional SSI rate was 2.3% in the primary analysis and 1.2% in those completing the protocol - No device-related adverse events were observed.

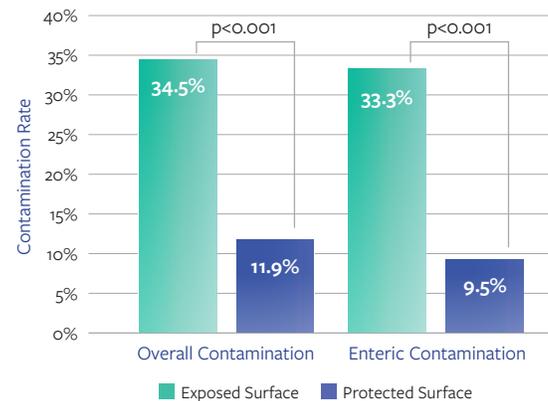


Figure 7: Summary of overall contamination and enteric results

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 Calculator²⁷

Papaconstantinou HT, Birnbaum EH, Ricciardi R, et al. Surgical Infections. 2018.

In a study comparing the observed rate of SSI using CleanCision in a prospective study to the predicted rate using the American College of Surgeons (ACS) National Surveillance Quality Improvement Program (NSQIP) Risk Calculator, the observed/expected ratio was 0.39, which demonstrates a **61% decrease in SSI with the use of the CleanCision device** (3.7% vs 9.5%, $p=0.04$).²⁷

Study Objective:	To evaluate the rate of surgical site infection observed when using the CleanCision device compared to the predicted rate for that patient population
Study Design:	A retrospective case-controlled study comparing the rate of SSI observed in a prospective cohort study using CleanCision to the predicted rate of SSI using the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) risk calculator
Subjects:	108 patients undergoing elective colorectal resection
Outcome Measures:	Rate of surgical site infection (SSI)
Results:	The observed/expected ratio for SSI was 0.39 demonstrating a 61% decrease in SSI with the use of the CleanCision device (3.7% vs 9.5%, $p=0.02$).

61% Reduction in Overall SSI vs. Predicted Risk ($p=0.04$)

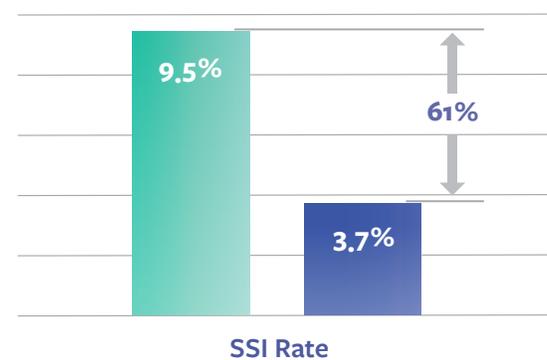


Figure 8: Comparison of Observed vs. NSQIP Predicted SSI Rates

Estimated Economic Impact to the Hospital

CleanCision is part of a broader set of new advanced infection control technologies. As hospitals try to assess these technologies, it is important to evaluate their overall economic impact. CleanCision is easily adopted into the current surgical workflow and has been demonstrated in a clinical study to reduce surgical site infections.²⁷ The observed clinical benefit can be translated into an economic analysis by utilizing SSI cost data reported in the literature. For similar per patient investment to other available advanced infection control technologies (e.g. negative pressure wound therapy), CleanCision shows a clear cost savings to the hospital. The estimated net hospital cost savings realized in the Papaconstantinou clinical study²⁷ utilizing the CleanCision technology in 108 patients is \$60,540.

The cost-effectiveness of the CleanCision device was also evaluated in a study using a decision-analytic model showing the device was cost-effective with a price threshold of over \$2,000, indicating that the **per patient cost savings to the hospital was at least \$2,000.**²⁸

Number of Patients	108
Expected Number of Infections ²⁷ (Based on 9.5% estimated SSI rate)	10
Observed Number of Infections ²⁷	4
Expected Total Infection Cost (Incremental cost of infection = \$19,000/patient ^{4,9})	\$190,000
Observed Total Infection Cost	\$76,000
Total Cost Savings (Expected – Observed Cost)	\$114,000
Cost of Advanced Technology	\$53,460
Net Total Savings (Total Savings – Cost of Therapy)	\$60,540

CleanCision is Cost-Effective

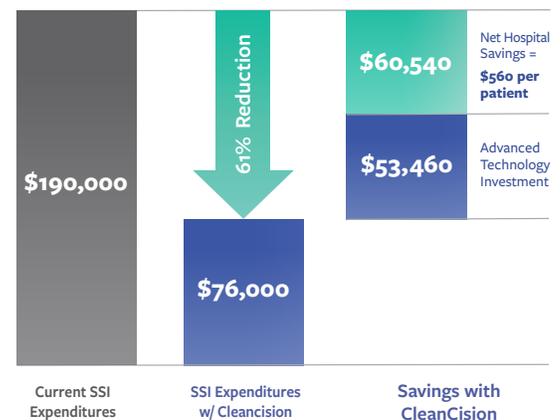


Figure 9: CleanCision Cost-Effectiveness (SSI Expenditures per 108 Colorectal Surgeries)

Conclusion:

The risk of surgical site infection is greater in high-risk abdominal procedures and requires new approaches that attack the root cause of those infections. The leading cause of SSI in abdominal surgery is contamination of the wound edges by enteric bacteria. While progress has been made in recent decades, surgical teams still struggle to comprehensively mitigate this risk. Current surgical technologies have not evolved to adequately eliminate contamination, creating critical gaps that expose patients to infection. Expanding existing SSI bundles to include “plus measures” such as CleanCision can support the drive towards zero preventable surgical infections.

Expanding existing SSI bundles to include “plus measures” such as CleanCision can support the drive towards zero preventable surgical infections.

This novel technology combines wound protection with wound irrigation and has been demonstrated in clinical trials to reduce intraoperative contamination and surgical site infection rates.^{24,27} Reductions in surgical site infections not only benefits the patients, but can also provide significant cost savings to the hospital.

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