

LET'S REDUCE SURGICAL SITE INFECTION TOGETHER

Applied Medical's Commitment to Reducing Surgical Site Infection

Surgical site infections (SSIs) have contributed \$3 billion to \$10 billion annually to the cost of healthcare.¹ With the constant threat to reimbursement and to patient safety, hospitals have aimed to combat SSI rates through systematic, defined processes.^{1,2,3}

To further our dedication to improving both hospital and patient outcomes, we are committed to being a part of the overall solution to reduce SSI through research, education and awareness. Our mission is to enhance patient outcomes by providing multiple platforms to discuss and implement clinically proven methods to reduce the incidence of SSI.

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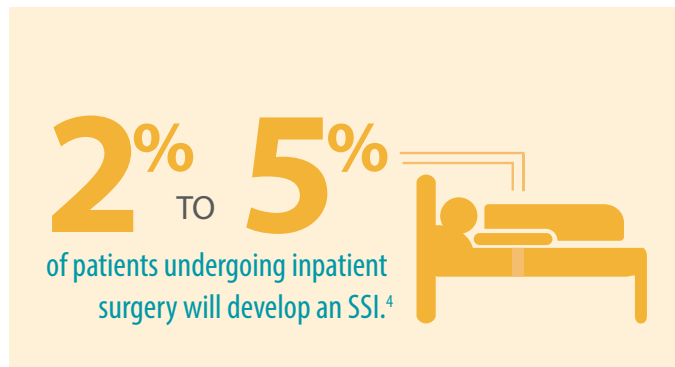
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The Impact of SSI on Hospitals



The Impact of SSI on Hospitals

Guidelines for Preventing SSI

One of various bundle elements included in an SSI protocol, the use of a wound protector has been recommended by numerous health organizations as a means of preventing SSI.

"The use of a wound protector at the extraction site and the irrigation of port sites and extraction site incisions may reduce abdominal wall cancer recurrences."

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

"Use impervious plastic wound protectors for gastrointestinal and biliary tract surgery."

The Society of Healthcare Epidemiology of America (SHEA)

"The use of an impervious plastic wound protector can prevent SSI in open abdominal surgery, and evidence is strongest for elective colorectal and biliary tract procedures (Guideline 2.8)."

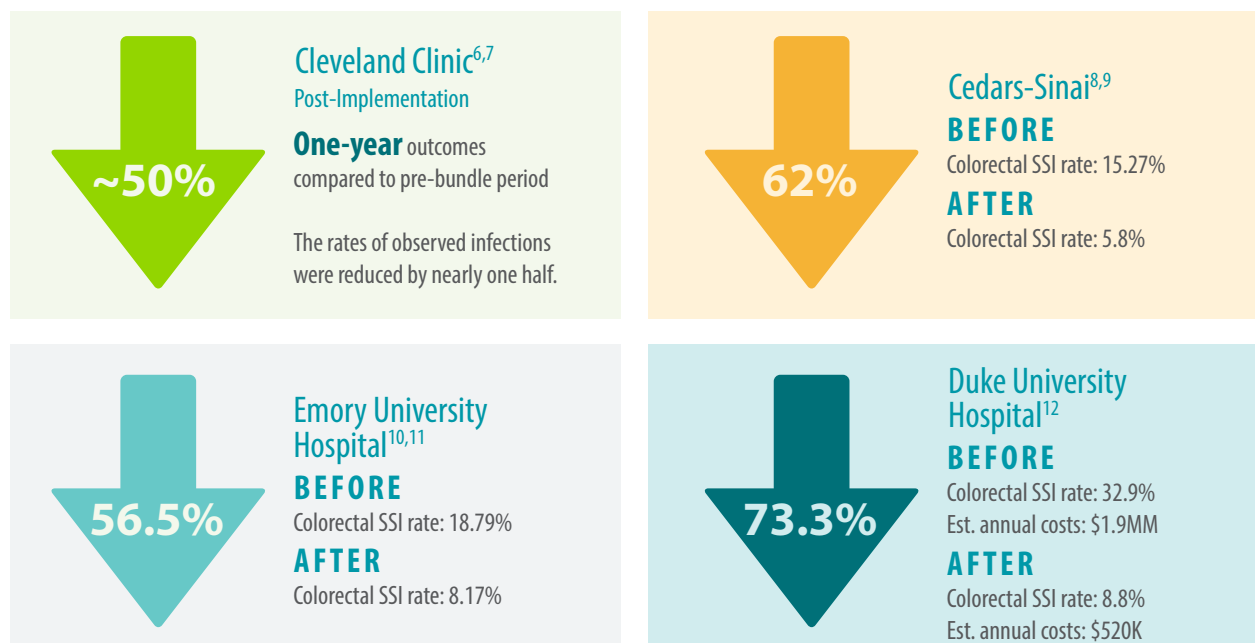
American College of Surgeons and Surgical Infection Society (ACS)

"The panel suggests considering the use of wound protector devices in clean-contaminated, contaminated and dirty abdominal surgical procedures for the purpose of reducing the rate of SSI."

World Health Organization (WHO)

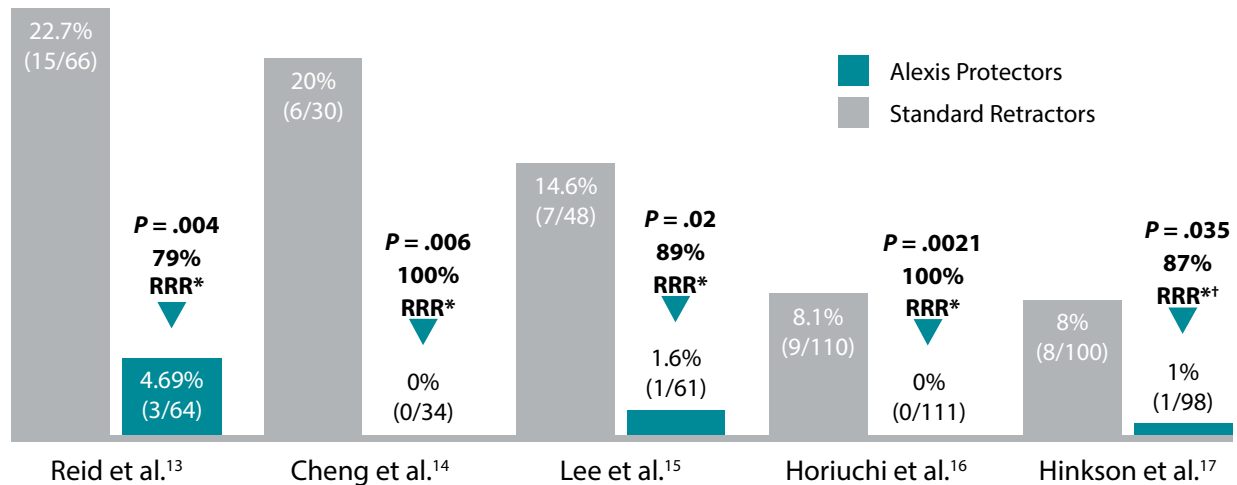
Successful SSI Prevention Bundles

The following facilities have demonstrated a nearly 50% reduction in SSIs after implementing an SSI prevention bundle that included Alexis protectors.



Clinical Evidence

Rate of Superficial Incisional Surgical Site Infections – Alexis® Protectors vs Standard Retractors



*RRR (relative risk reduction) was defined as the proportion of the control group (standard retractors) experiencing a given outcome minus the proportion of the treatment group (Alexis protectors) experiencing the outcome, divided by the proportion of the control group (standard retractors) experiencing the outcome.
 †The data reflects both superficial and deep incisional and organ space SSI.

Colorectal

Wound protectors in reducing surgical site infections in lower gastrointestinal surgery: An updated meta-analysis.²²

“Our meta-analysis found that dual-ring wound protectors reduce the odds of SSI in patients undergoing lower gastrointestinal surgery. . . .”

“. . . We demonstrated evidence of a subgroup difference where dual-ring wound protectors reduced SSIs while single-ring retractors did not, which provides greater insight in the choice of wound protection devices.”

Wound protectors reduce surgical site infection: A meta-analysis of randomized controlled trials.²³

“Our study suggests that the use of wound protectors decreases the risk of SSI by 45%. Our number needed to treat suggests that only 10 patients would have to be treated intraoperatively with a wound protector to prevent 1 SSI.”

Clinical Evidence

Barrier wound protection decreases surgical site infection in open elective colorectal surgery: A randomized clinical trial.¹³

"In this study the use of barrier wound protection in elective open colorectal resectional surgery resulted in a clinically significant reduction in incisional surgical site infections."

"There was a significant reduction in the incidence of incisional surgical site infections when the wound protector was used: 3 of 64 (4.7%) vs 15 of 66 (22.7%); P = .004."

ALEXIS O-Ring wound retractor vs conventional wound protection for the prevention of surgical site infections in colorectal resections.¹⁴

"Superficial incisional SSI was significantly diminished in the ALEXIS wound retractor group (P=0.006)."

Randomized, controlled investigation of the anti-infective properties of the Alexis retractor/protector of incision sites.¹⁶

Wound infection decreased by 100% in the With Alexis retractor group. (The wound infection rate was 0% for the With Alexis group, versus 8.1% for the Without Alexis group.)

Plastic wound retractors as bacteriological barriers in gastrointestinal surgery: A prospective multi-institutional trial.¹⁹

"[U]se of a plastic wound retractor may result in reduced enteric bacterial colonization of the surgical incision site during gastrointestinal surgery. Reduced colonization of the surgical incision site by enteric bacteria due to the use of a plastic wound retractor should result in a reduction in SSI following gastrointestinal surgery."

General

Efficacy of a dual-ring wound protector for prevention of surgical site infections after pancreaticoduodenectomy in patients with intrabiliary stents: A randomized clinical trial.²⁴

"Among adult patients with intrabiliary stents, the use of a dual-ring wound protector during pancreaticoduodenectomy significantly reduces the risk of incisional SSI."

Use of wound-protection system and postoperative wound-infection rates in open appendectomy:
A randomized prospective trial.¹⁵

The study was terminated early, with 109 of 300 cases studied, after an interim analysis showed a significant reduction in infection (89%) when the Alexis retractor was used. (The rate of infection was 1.6% for the wound protection arm of the study, versus 14.6% for the traditional retraction arm.)

C-Section

Surgical site infection in cesarean sections with the use of a plastic sheath wound retractor compared to the traditional self-retaining metal retractor.¹⁷

"[T]he use of plastic-sheath wound retractors such as the Alexis® O C-Section Retractor compared to the traditional Collins self-retaining metal retractor in low risk women, having the first cesarean is associated with a significantly reduced risk of surgical site infection.

"There is significant reduction in the use of electric cautery for subcutaneous bleeding, bowel handling and postoperative pain. Operator satisfaction is improved and postoperative pain is less."

ARE Alexis
PRODUCTS
PART OF YOUR
STANDARD
OF CARE?

Product Information

The Alexis wound protector

... offers 360-degree protection:

- Reduces surgical site infection.¹³⁻¹⁷
- Shields the incision site from bacterial invasion.¹⁸⁻¹⁹
- Maintains moisture to promote healing.²⁰

... provides 360-degree atraumatic retraction:

- Allows for maximum exposure with a minimal incision size.
- Offers unparalleled exposure without the trauma and pain associated with prolonged point retraction.
- Provides retraction hands-free, reducing the strain, discomfort and fatigue associated with traditional hand-held retractors.²¹
- Creates a tamponade effect to minimize blood loss.¹⁷

... offers adaptability and versatility:

- Accommodates a wide range of specialties, patient sizes and incision sizes.
- Facilitates rapid and effortless setup.

Alexis O

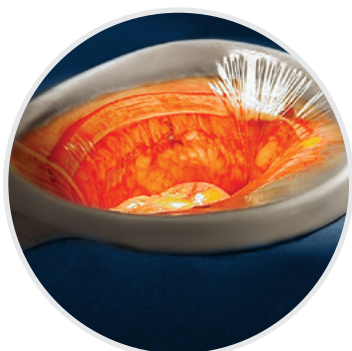
Wound Protector-Retractor



Featuring a rigid retraction ring for maximum exposure

Alexis

Wound Protector-Retractor



Featuring a flexible retraction ring for anatomical conformity

Alexis O

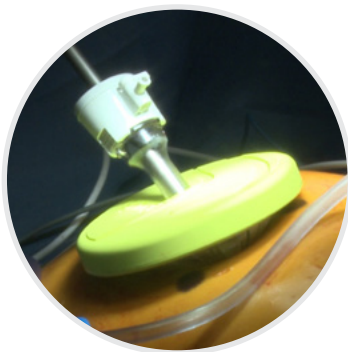
C-Section Protector-Retractor



Featuring a rigid retraction ring for maximum uterine exposure

Alexis

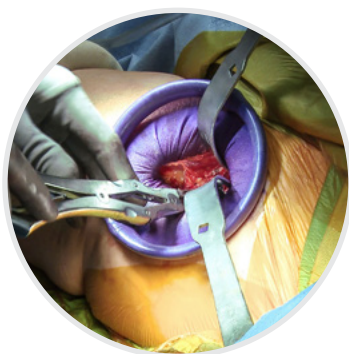
Laparoscopic System



Featuring a laparoscopic cap to facilitate specimen extraction

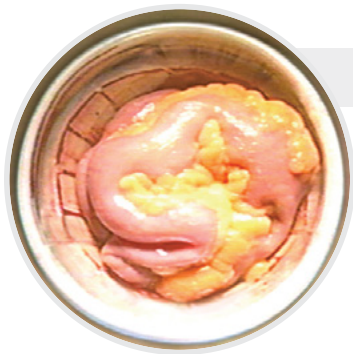
Alexis

Orthopaedic Protector



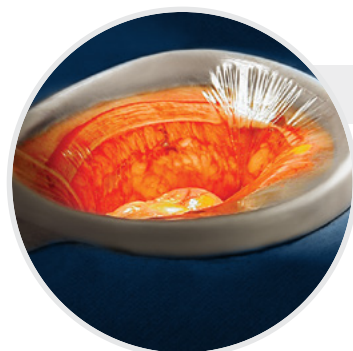
Featuring a rigid retraction ring for maximum retraction and a flexible retraction ring for maximum versatility

Procedural Applications



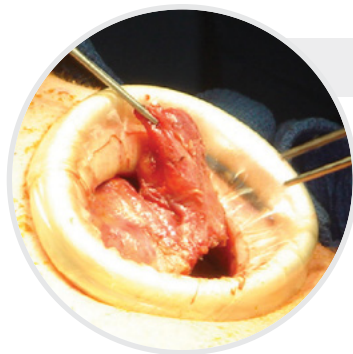
Colon and Rectal

Lap colectomy (S and M laparoscopic system)
Open colectomy (L, XL, XXL, XXXL)



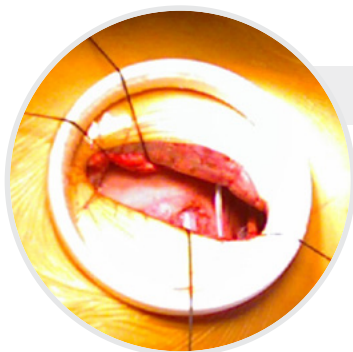
Bariatric

Lap gastric bypass (XS, S)
Open gastric bypass (L, XL)



General

Inguinal hernia repair (XS, S)
Thyroidectomy (XS, S)
Appendectomy (S, M)
Splenectomy (L, XL)
Pancreatectomy (L, XL)
Whipple (L, XL, XXL, XXXL)



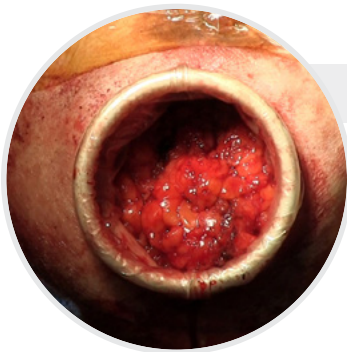
Cardiothoracic

Video-assisted thoracoscopic surgery (VATS) (XXS, XS, S)
Mitral valve repair or replacement (S, M)
Thoracotomy (S, M)



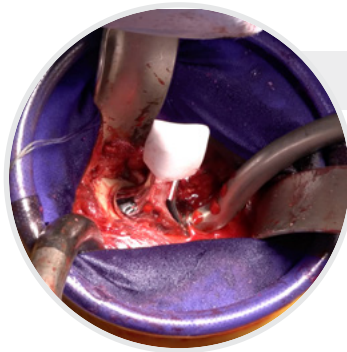
OB/GYN

- Postpartum tubal ligation (XXS, XS)
- Bilateral salpingo-oophorectomy (XS, S)
- Lap hysterectomy (S and M laparoscopic system)
- Mini-laparotomy (S, M)
- Myomectomy (S, M)
- Total abdominal hysterectomy (S, M, L)
- Cesarean section (L, XL)



Breast

- Lumpectomy (XS, S)
- Mastectomy (S, M)
- Sentinel lymph node biopsy (XXS, XS, S)



Orthopaedic

- Total shoulder arthroplasty (XS/M, S/S, S/M)
- Total hip arthroplasty (S/M, M/L)

Reorder Information



Alexis O Wound Protector-Retractors

Featuring a rigid retraction ring for maximum exposure

Reorder No.	Size	Sheath Length	Incision Range	Qty/Box
C8401*	Small	18cm	2.5–6cm	5
C8402	Medium	18cm	5–9cm	5
C8403	Large	25cm	9–14cm	5
C8404	Extra Large	34cm	11–17cm	5
C8405	Extra Extra Large	36cm	17–25cm	5
C8406	Extra Extra Extra Large	39cm	25–32cm	3



Alexis Wound Protector-Retractors

Featuring a flexible retraction ring for anatomical conformity

Reorder No.	Size	Sheath Length	Incision Range	Qty/Box
C8313*	Extra Extra Small	20cm	1–3cm	5
C8323*	Extra Extra Small, Short	11cm	1–3cm	5
C8312*	Extra Small	19cm	2–4cm	5
C8322*	Extra Small, Short	13cm	2–4cm	5
C8301*	Small	18cm	2.5–6cm	5
C8302	Medium	18cm	5–9cm	5
C8303	Large	25cm	9–14cm	5
C8304	Extra Large	34cm	11–17cm	5



Alexis O C-Section Protector-Retractors

Featuring a rigid retraction ring for maximum uterine exposure

Reorder No.	Size	Sheath Length	Incision Range	Qty/Box
G6313	Large	25cm	9–14cm	5
G6314	Extra Large	34cm	11–17cm	5

*Models including a tether to facilitate device removal



Alexis Laparoscopic Systems

Featuring a laparoscopic cap to facilitate specimen extraction

Reorder No.	Size	Sheath Length	Incision Range	Qty/Box
C8501*	Small	18cm	2.5–6cm	6
C8502	Medium	18cm	5–9cm	6



Alexis Orthopaedic Protectors

Featuring a rigid retraction ring for maximum retraction and a flexible retraction ring for maximum versatility

Reorder No.	Size	Sheath Length	Incision Range	Qty/Box
<i>Rigid Retraction Ring</i>				
HR000	Extra Small/Medium	14cm	2.5–7cm	5
HR001	Small/Small	14cm	2.5–8cm	5
HR004	Small/Medium	14cm	2.5–8cm	5
HR005	Medium/Large	17cm	5–13cm	5
<i>Flexible Retraction Ring</i>				
HR100	Extra Small/Medium	14cm	2.5–7cm	5
HR101	Small/Small	14cm	2.5–8cm	5
HR104	Small/Medium	14cm	2.5–8cm	5
HR105	Medium/Large	17cm	5–13cm	5

*Models including a tether to facilitate device removal

References

1. Scott RD. The direct medical costs of healthcare-associated infections in U.S. hospitals and the benefits of prevention. March 2009. Accessed November 30, 2015. <https://stacks.cdc.gov/view/cdc/11550>
2. Harris R. Analysis of surgical site infection rates and cost benefits associated with plain gauze dressings compared to gauze dressings impregnated with Polyhexamethylene Biguanide (PHMB). *Am J Infect Control*. 2008;36(5):E31-E32. doi:10.1016/j.ajic.2008.04.218
3. Kirkland KB, Briggs JP, Trivette SL, Wilkinson WE, Sexton DJ. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. *Infect Control Hosp Epidemiol*. 1999;20(11):725-730. doi:10.1086/501572
4. Anderson DJ, Podgorny K, Berríos-Torres SI, et al. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. *Infect Control Hosp Epidemiol*. 2014;35(6):605-627. doi:10.1086/676022
5. Klevens RM, Edwards JR, Richards CL Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Rep*. 2007;122(2):160-166. doi:10.1177/003335490712200205
6. Cleveland Clinic. Bundled Care Program Cuts Colorectal Surgical Site Infection Rates in Half. Consult QD. September 24, 2015. Accessed October 14, 2015. <https://consultqd.clevelandclinic.org/bundled-care-program-cuts-colorectal-surgical-site-infection-rates-in-half/>
7. Gorgun E. SSI bundles skin prep, oral antibx/bowel prep wound protector. Oral presentation at: Reducing SSI: Take action with evidence; May 2, 2014; Baltimore, MD.
8. Patterson P. Joint project targets prevention for colorectal surgical infections. *OR Manager*. 2013;29(1):6-7.
9. Murthy R. Implementing a bundle to reduce colorectal surgical site infection. Oral presentation at: 34th Annual Meeting of the Surgical Infection Society; May 1-3, 2014; Baltimore, MD.
10. Sullivan P, Castleberry C, Tripathi S. SSI prevention checklist – Colorectal protocol. Emory Healthcare. Accessed October 5, 2015. <http://www.med.emory.edu/education/vme/SSIPrevention/Colorectal/index.html>
11. Sharma J. Implementation of a NSQIP based wound infection prevention process (WIPP) reduces surgical site infections. Talk presented at: Reducing SSI: A roadmap to successful implementation; June 28, 2015; Nashville, TN.
12. Salwachter AR, Freischlag JA, Sawyer RG, Sanfey HA. Economic impact of the preventative surgical site bundle in colorectal surgery. Paper presented at: ACS NSQIP National Conference; July 13-16, 2013; San Diego, CA.
13. Reid K, Pockney P, Draganic B, Smith SR. Barrier wound protection decreases surgical site infection in open elective colorectal surgery: a randomized clinical trial. *Dis Colon Rectum*. 2010;53(10):1374-1380. doi:10.1007/DCR.0b013e3181ed3f7e
14. Cheng KP, Roslani AC, Sehha N, et al. ALEXIS O-Ring wound retractor vs conventional wound protection for the prevention of surgical site infections in colorectal resections(1). *Colorectal Dis*. 2012;14(6):e346-e351. doi:10.1111/j.1463-1318.2012.02943.x
15. Lee P, Waxman K, Taylor B, Yim S. Use of a wound protection system and postoperative wound infection rates in open appendectomy: A randomized prospective trial. *Arch Surg*. 2009;144(9):872-875. doi:10.1001/archsurg.2009.151
16. Horiuchi T, Tanishima H, Tamagawa K, et al. Randomized, controlled investigation of the anti-infective properties of the Alexis retractor/protector of incision sites. *J Trauma*. 2007;62(1):212-215. doi:10.1097/01.ta.0000196704.78785.ae
17. Hinkson L, Siedentopf JP, Weichert A, Henrich W. Surgical site infection in cesarean sections with the use of a plastic sheath wound retractor compared to the traditional self-retaining metal retractor. *Eur J Obstet Gynecol Reprod Biol*. 2016;203:232-238. doi:10.1016/j.ejogrb.2016.06.003
18. Horiuchi T, Tanishima H, Tamagawa K, et al. A wound protector shields incision sites from bacterial invasion. *Surg Infect (Larchmt)*. 2010;11(6):501-503. doi:10.1089/sur.2009.072
19. Mohan HM, McDermott S, Fenelon L, et al. Plastic wound retractors as bacteriological barriers in gastrointestinal surgery: a prospective multi-institutional trial. *J Hosp Infect*. 2012;81(2):109-113. doi:10.1016/j.jhin.2012.03.005
20. Horiuchi T, Nakatsuka S, Tanishima H, et al. A wound retractor/protector can prevent infection by keeping tissue moist and preventing tissue damage at incision sites. *Helix Review Series: Infectious Diseases*. 2007;(3):17-23.
21. Spera P, Lloyd JD, Hernandez E, et al. AORN Ergonomic Tool 5: Tissue Retraction in the Perioperative Setting. *AORN J*. 2011;94(1):54-58. doi:10.1016/j.aorn.2010.08.031
22. Zhang L, Elsolh B, Patel SV. Wound protectors in reducing surgical site infections in lower gastrointestinal surgery: an updated meta-analysis. *Surg Endosc*. 2018;32(3):1111-1122. doi:10.1007/s00464-017-6012-0
23. Edwards JP, Ho AL, Tee MC, Dixon E, Ball CG. Wound protectors reduce surgical site infection: a meta-analysis of randomized controlled trials. *Ann Surg*. 2012;256(1):53-59. doi:10.1097/SLA.0b013e3182570372
24. Bressan AK, Aubin JM, Martel G, et al. Efficacy of a Dual-ring Wound Protector for Prevention of Surgical Site Infections After Pancreaticoduodenectomy in Patients With Intrahepatic Stents: A Randomized Clinical Trial. *Ann Surg*. 2018;268(1):35-40. doi:10.1097/SLA.0000000000002614

