



REDUCING SURGICAL SITE INFECTION

**Alexis<sup>®</sup> O Wound Protector/Retractor**

***“Programs that reduce the incidence of SSI can substantially decrease morbidity and mortality and reduce the economic burden for patients and hospitals.”***

Kirkland K., MD., et al. The Impact of Surgical-Site Infections in the 1990s: Attributable Mortality, Excess Length of Hospitalization, and Extra Costs. *Infect Control Hosp Epidemiol* 1999; 20:725-730.

## Healthcare Impact

- SSI has added **\$3 to \$10 billion** to the cost of healthcare<sup>1</sup>
- **2% to 5%** of patients undergoing inpatient surgery will develop an SSI<sup>2</sup>
- There were over **290,000** cases of SSI in 2002, which resulted in over 8,000 deaths<sup>3</sup>

## Patient Impact

On average, SSI patients:

- Spend an additional **7-10 days** in the hospital<sup>4</sup>
- Are **60%** more likely to spend time in ICU<sup>5</sup>
- Are **5 times** more likely to be readmitted to the hospital<sup>5</sup>
- Have a **2-11 times** higher risk of death than patients without an SSI<sup>4</sup>
- Require an additional cost of **\$11,087 to \$34,670** per infection<sup>1</sup>

1. Scott, R. Douglas. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. March 2009.

[http://www.cdc.gov/HAI/pdfs/hai/Scott\\_CostPaper.pdf](http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf).

2. Anderson DJ, et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals. Infect Control Hosp Epidemiol. 2008; 29: S51-S61 for individual references.

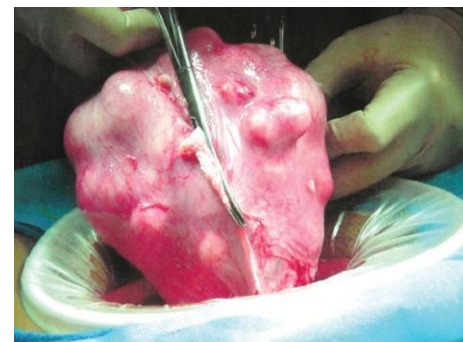
3. Kleven RM, et al. Estimating Healthcare-Associated Infections and Deaths in U.S. Hospitals, 2002. Public Health Rep. 2007; 122: 160-166.

4. Anderson DJ, et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals. Infect Control Hosp Epidemiol. 2008; 29: S51-S61 for individual references.

5. Kirkland K., MD., et al. The Impact of Surgical-Site Infections in the 1990s: Attributable Mortality, Excess Length of Hospitalization, and Extra Costs. Infect Control Hosp Epidemiol. 1999; 20: 725-730.

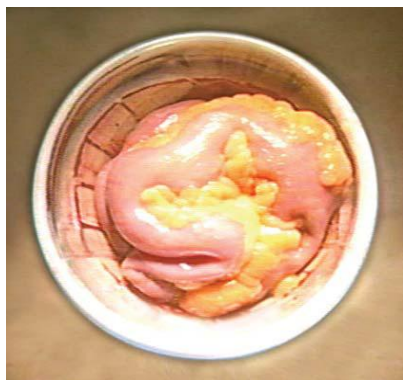
## Protection

- Significantly decreases risk of wound infection
- 360° of wound protection
- Maintains moisture at the incision site



## Retraction

- 360° of circumferential retraction
- Distributes force evenly, eliminating point trauma and associated pain



## Exposure

- Maximizes exposure, minimizes incision size
- Allows visualization of wound margins
- Frees up valuable hands in the Operating Room



# Clinical Evidence



Edwards J. P., MD, MPH, CPH., et al. Wound Protectors Reduce Surgical Site Infection: A Meta-Analysis of Randomized Controlled Trials. Ann Surg. 2012 Jul; 256(1): 53-59.

***“Impervious plastic wound protectors reduce the risk of SSI when employed in non-trauma-related gastrointestinal and biliary tract surgery. Wound protectors represent a safe and simple intervention that may reduce postoperative morbidity and mortality.”***

***“There was a nonsignificant trend toward greater protective effect in studies using a dual ring protector (RR = 0.31, 95% CI 0.14-0.67, P = 0.003), rather than a single ring protector (RR = 0.83, 95% CI 0.38-1.83, P = 0.64).”***



Cheng K. P., et al. ALEXIS O-Ring wound retractor vs conventional wound protection for the prevention of surgical site infections in colorectal resections. Colorectal Dis. 2012 Jun; 14(6): 346-351.

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

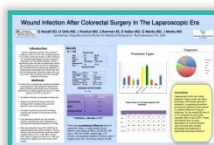
***“The ALEXIS wound retractor is more effective in preventing SSI in elective colorectal resections compared with conventional methods.”***



Mohan H. M., et al. Plastic wound retractors as bacteriological barriers in gastrointestinal surgery: a prospective multi-institutional trial. J Hosp Infect. 2012 Jun; 81(2): 109-113. Epub 2012 May 11.

***“[E]nteric organisms were cultured twice as often from the inside surface of the retractor compared with the outside surface of the retractor (49% vs 26%, respectively; P < 0.0001).”***

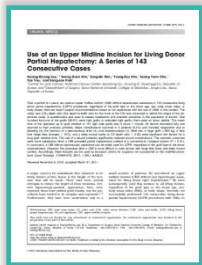
***“[U]se of a plastic wound retractor may result in reduced enteric bacterial colonization of the surgical incision site during gastrointestinal surgery. Reduced colonization of the surgical incision site by enteric bacteria due to the use of a plastic wound retractor should result in a reduction in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



Nassif G., DO., et al. Wound Infection After Colorectal Surgery In The Laparoscopic Era. SAGES Poster Session 2012.

***“Laparoscopic colon and rectal resection using a clean and dirty technique, with sterile specimen extraction, re-gowning procedure and wound protection have proven to reduce the incidence of wound infections, for an overall SSI rate of 5.1% compared to previously reported rates of up to 30%.”***

# Clinical Evidence



Lee K.-W., et al. Use of an Upper Midline Incision for Living Donor Partial Hepatectomy: A Series of 143 Consecutive Cases. Liver Transpl. 2011 Aug; 17(8): 969-975.

***“Only the use of a wound protector was found to significantly reduce the risk of wound infections in an adjusted analysis.”***



Horiuchi T., MD, PhD., et al. A Wound Protector Shields Incision Sites from Bacterial Invasion. Surg Infect (Larchmt). 2010 Dec; 11(6): 501-503. Epub 2010 Sep.

***“These results suggest that the [wound protector] protects an incision site from bacterial invasion.”***

***“[W]e consider that the low incidence of SSI may have resulted from the protective effects of the [wound protector].”***



Reid K., B.Med., et al. Barrier Wound Protection Decreases Surgical Site Infection in Open Elective Colorectal Surgery: A Randomized Clinical Trial. Dis Colon Rectum. 2010 Oct; 53(10): 1374-1380.

***“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%).”***



Lee P., MD., et al. Use of Wound-Protection System and Postoperative Wound-Infection Rates in Open Appendectomy. Arch Surg. 2009 Sep; 144(9): 872-875.

***“Our data demonstrate that a statistically significant reduction in the incidence of wound infection was achieved with the use of a wound-protection device. This device provides a simple intervention that may eventually have a large impact on the incidence of surgical wound infection and therefore annual health care expenditures.”***



# Clinical Evidence



Nunn A., MD., et al. A Novel Approach to Preventing Wound Infections in Laparoscopic Roux-En-Y Gastric Bypass Patients. SAGES Poster Session 2008.

***"The wound infection rate of the [left upper quadrant] trocar site was significantly decreased when utilizing the wound retractor (18% to 0%)."***



Horiuchi T., MD. PhD., 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.

***"We found that the wound retractor/protector prevented the incision site from drying, decreased tissue damage, and facilitated the migration of neutrophils, suggesting a preventive effect of the device with respect to wound infection."***

***"The studied wound retractor/protector effectively protects wound tissue from damage due to environmental factors experienced during surgery."***



Horiuchi T., MD. PhD., et al. Randomized Controlled Investigation of the Anti-Infective Properties of the Alexis Retractor/Protector of Incision Sites. J Trauma. 2007 Jan; 62(1): 212-215.

***"The results of this study demonstrate that wound infection decreased significantly in the With Alexis retractor group."***

***"It was suggested that the use of the Alexis wound retractor would protect surgical wounds from contamination by bacteria and thus prevent infection."***



Im A., MD., et al. Infection Rates Using Protectors in Laparoscopic Gastric Bypass. SAGES Poster Session 2005.

***"We have noticed a decrease in the incidences of wound infection after using the wound protector at our trocar site."***



Facility/System Name: *Sample Facility*  
City, State: *Rancho Santa Margarita, CA*

Presented By: *Applied Medical Representative*

| Current Infection Analysis  |                 |
|---|-----------------|
|   | Sample Facility |
| Annual Colorectal Procedures                                      | 360             |
| Facility Colorectal Surgical Site Infection Rate                  | 5.90%           |
| Annual Colorectal Surgical Site Infections                        | 21              |
| Average Cost of a Colorectal Surgical Site Infection <sup>1</sup> | \$11,087        |
| Annual Cost of Colorectal Surgical Site Infections                | \$232,827       |

| Projected Infection Reduction with Alexis O Wound Protector  |                                      |
|--|--------------------------------------|
|  | 50% Infection Reduction <sup>2</sup> |
| Reduced Infection Rate with Alexis O Protector               | 2.95%                                |
| Annual Colorectal Surgical Site Infections                   | 11                                   |
| Annual Cost of Colorectal Surgical Site Infections           | \$121,957                            |
| Annual Cost of Alexis O Protectors for Colorectal Procedures | \$24,120                             |

| Financial Impact                               |                            |               |
|--|----------------------------|---------------|
| Investment in Alexis SSI Prevention Initiative | Savings in Colorectal SSIs | TOTAL SAVINGS |
| \$24,120                                       | \$110,870                  | \$86,750      |

1. A March 2009 CDC report by R. Douglas Scott, "The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention," used published medical and economic literature to establish a low and high estimate per patient SSI of \$11,087 and \$34,670. Original studies cited:

\*\$11,087 (\$10,443 2005 dollars). Anderson, D., MD, MPH, et al. Underresourced Hospital Infection Control and Prevention Programs: Penny Wise, Pound Foolish? *Infect Control Hosp Epidemiol* 2007; 28:767-773.

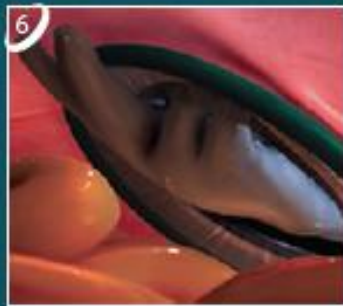
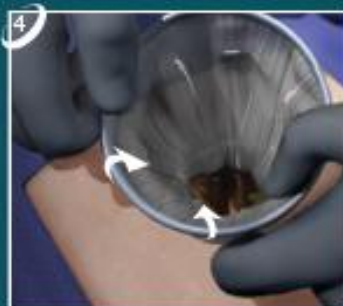
\*\$34,670 (\$23,546 2002 dollars). Stone PW, et al. Systematic review of economic analyses of health care-associated infections. *Am J Infect Control* 2005;33:501-509.

2. Clinical studies have shown that the use of the Alexis O Protector in colorectal procedures reduced the occurrence of surgical site infection among patients between 79-100%. The above cost value analysis demonstrates savings based on a conservative 50% reduction in colorectal SSI rates.

\*Reid K., B.Med., et al. Barrier Wound Protection Decreases Surgical Site Infection in Open Elective Colorectal Surgery: A Randomized Clinical Trial. *Dis Colon Rectum*. 2010 Oct; 53(10): 1374-1380.

\*Horiuchi T., MD, PhD., et al. Randomized Controlled Investigation of the Anti-Infective Properties of the Alexis Retractor/Protector of Incision Sites. *J Trauma*. 2007 Jan; 62(1): 212-215.



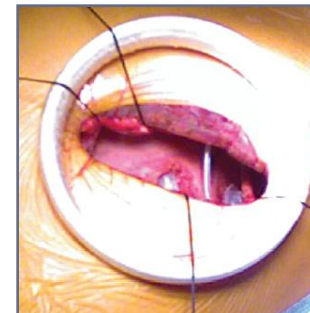
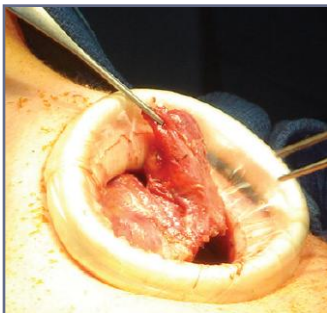


Prepare the surgical site according to standard procedure, making sure the skin is clean and dry.

1. Place the template over the incision site, and mark an appropriate length incision line using a sterile marker.
2. Make an incision along the marked incision line.
3. Insert the green ring of the Alexis O wound retractor into the operative site.
4. Gently grasp the white retraction ring of the Alexis O retractor at the 10 o'clock and 2 o'clock position and roll inward.
5. Repeat until ultimate retraction is obtained.
6. Carefully check to ensure that no bowel or tissue entrapment has occurred.
7. Perform procedure through 360° retracted and protected incision site.
8. Retrieve the Alexis O retractor by simply removing the green inner ring from the peritoneal cavity.

# The Alexis wound protectors are indicated for soft tissue and thoracic retraction

- Post Partum Tubal Ligation (XXS/XS)
- Bilateral Salpingo Oophorectomy (XS/S)
- Thyroidectomy (XS/S)
- Video-Assisted Thoracoscopic Surgery (VATS) (XXS/XS/S)
- Thoracotomy (S/M)
- Appendectomy (S/M)
- Myomectomy (S/M)
- Lap Colectomy (S/M)
- Mini-Laparotomy (S/M)
- Total Abdominal Hysterectomy (S/M/L)
- Mitral Valve Repair/Replacement (S/M)
- Cesarean Section (L/XL)
- Open Gastric Bypass (L/XL)
- Splenectomy (L/XL)
- Open Colon (L/XL)
- Pancreatectomy (L/XL)



# Breadth of Product Lines

## Alexis O Wound Protector/Retractor



Featuring a rigid retraction ring for superior exposure

| Reorder No. | Size               | Qty   |
|-------------|--------------------|-------|
| C8401       | Small, 2.5 – 6cm   | 5/box |
| C8402       | Medium, 5 – 9 cm   | 5/box |
| C8403       | Large, 9 – 14cm    | 5/box |
| C8404       | X-Large, 11 – 17cm | 5/box |

## Alexis O C-Section Retractor



Featuring a rigid retraction ring for superior exposure

| Reorder No. | Size               | Qty   |
|-------------|--------------------|-------|
| G6313       | Large, 9 – 14cm    | 5/box |
| G6314       | X-Large, 11 – 17cm | 5/box |

## Alexis Laparoscopic System



Featuring a rigid retraction for superior exposure

| Reorder No. | Size             | Qty   |
|-------------|------------------|-------|
| C8701       | Small, 2.5 – 6cm | 5/box |
| C8702       | Medium, 5 – 9 cm | 5/box |

## Alexis Wound Protector/Retractor



Featuring a flexible retraction ring for maximum conformity

| Reorder No. | Size               | Qty   |
|-------------|--------------------|-------|
| C8313       | XX-Small, 1 – 3cm  | 5/box |
| C8312       | X-Small, 2 – 4cm   | 5/box |
| C8301       | Small, 2.5 – 6cm   | 5/box |
| C8302       | Medium, 5 – 9 cm   | 5/box |
| C8303       | Large, 9 – 14cm    | 5/box |
| C8304       | X-Large, 11 – 17cm | 5/box |

## Alexis Orthopaedic Protector



Featuring a rigid retraction ring for superior exposure

| Reorder No. | Size                    | Qty   |
|-------------|-------------------------|-------|
| HR001       | Small/Small, 2.5 – 8cm  | 5/box |
| HR004       | Small/Medium, 2.5 – 8cm | 5/box |
| HR005       | Medium/Large, 5 – 13cm  | 5/box |